Excerpts from the Deposition of Desiree Wheeler

EXHIBIT 11

IN THE UNITED STATES COURT
OF FEDERAL CLAIMS

ACLR, LLC	*	
	*	
Plaintiff	*	
	*	Civil Action
v.	*	
	*	No. 15-767
THE UNITED STATES	*	
	*	(Judge Campbell-Smith)
Defendant	*	

* * * * * * * * * *

Pursuant to Notice, the deposition of DESIREE WHEELER was taken on Wednesday, September 27th, 2017, commencing at 11:37 a.m., at HHS Office of General Counsel, 7500 Security Boulevard, Central Building, Room C2-01-17, Baltimore, Maryland 21244, before Kelly A. Taylor, Notary Public.

Reported by: Kelly A. Taylor

Q And did ACLR get paid a percentage of the amount of improper payments recovered under the Part D RAC contract?

A They got paid, they were supposed to get paid a percentage of, yes, their improper payment recoveries.

Q Did ACLR get paid if CMS didn't allow ACLR to pursue improper payments?

A Can you restate that?

Q Sure. If CMS didn't allow ACLR to pursue the recovery of improper payments, would CMS -- I'm sorry, let me restate it. If CMS did not allow ACLR to pursue a recovery of improper payments under the Part D RAC contract, would ACLR have been paid anything under the Part D RAC contract?

A So under this particular contract type ACLR was only paid based on recoveries so --

Q In order --

A -- in order to get paid they had to do recoveries. They would get a percentage of recoveries.

Q And if they couldn't pursue recoveries then they wouldn't get paid, correct?
A That sounds correct.
Q Whose responsibility under the Part D RAC contract was it to recover improper payments?
A Whose -- restate, please.
Q Whose responsibility under the Part D RAC contract was it to recover improper payments?
A ACLR.
MR. BONELLO: Let's mark this as exhibit 39. Again, for these depositions, for the depositions that ACLR is taking in this case we're just going to run the exhibits sequentially, we've agreed that's acceptable from DOJ's position. So we left off last deposition at 38, so this will be Exhibit 39.
(Exhibit 39 marked.)
Q I'm showing you what's been marked as Exhibit 39, can you identify this e-mail chain?
(Pause for document examination.)
A Yes.
Q Can you tell me what's going on in the

that they shouldn't do it. We should definitely follow-up with a contractual document, yes.

Q So if there's a right for a contractor to do something in a contract --

A Uh-huh.

Q -- the government can tell them not to comply with the contract and subsequently do a modification that then takes away the contractor's right?

A So there is ways that we can tell them not to do something. We could have issued a technical direction letter. There is ways that we should tell them not to do something.

Q Tell me as contracting officer what would be the ways that the government could in this situation preclude ACLR from sending out demand letters to plan sponsors for improper payment?

A So if it was something urgent then the contractor should receive a phone call from the contracting officer, as long as I follow up immediately with a contractual document.

Q And how soon would you have to do that,

what would be appropriate?

A I don't know that is there a timeline written anywhere, but I would think as soon as possible.

Q Would that be a week, a month, two months?

A Again, I can't give you a time. It just all depends on what the circumstances and the issues are. Like if it was life threatening it should be immediately, but if it's something that you agree to with the contractor and as long as you have verbal agreement, which is sometimes just as good as written agreement, then as long as you have to agreement then you should do it as soon as possible.

Q So there has to be an agreement between the government and the contractor in order to modify the contract, isn't that true?

MR. PORADA: Objection to form.

A Not in all instances.

Q Government can unilaterally modify the contract?

worked out the modifications we will have another phone call so at least we all know where we are in the process.

FEMALE VOICE: That's fine. Chris, are you willing to -- is that acceptable?

MALE VOICE: I will get on a plane tonight and be there tonight to, to address this issue. I don't, I don't -- I understand what you all of saying, but I don't think you understand the position I'm being placed in. I mean there are certain requirements that I have to go through to make sure that, if nothing else, if nothing does happen on this, if I don't get my base period, if I don't get a contract modification, that I have to do to at least assure that I get some remuneration for my efforts. I have to have some recourse. Everything that I have done up until this date has been in full performance of the contract and I'm now being told not to execute my contract, and I have a fully executable contract. I under -- and I can begin working on Monday, or sending out demand letters on Monday. I know from the program office

perspective you don't want that to happen. I don't want Desiree to come back and say okay, Chris, I'm going to issue a cease and desist and kick you to the curb either, okay. But I have an executable contract and if I don't execute that, that has additional problems for me. If I have --

FEMALE VOICE: I think you hear the contracting officer and program personnel telling you that you know, we don't think that's in the best interest for you to do that, so I think we all stand by that that we don't think it's in the best interest for you do that until we work out all of the issues to be resolved.

MALE VOICE: Desiree, and I'm not saying that --

Q Who was the last person that was speaking there?

A Desiree.

Q That's you?

A Uh-huh. Yes.

Q And when you say in the call it's not in the best interest for you to do that, you meant it

wasn't in the best interest of ACLR to send out demand letters, correct?

A I was saying it's in your statement of work that you can do, I'm not saying that you can't do, but it's not the best interest that you did do it. I think that's what I was saying.

Q What did you mean it's not in the best interest?

A The program office was saying they didn't want him to do it, it was simply reinforcing that we didn't think he should do it.

Q Even though ACLR had the right to do that under the Part D RAC contract, correct?

MR. PORADA: Objection to form.

A Correct.

Q Was there anything in the Part D RAC contract which made it not in the best interest of the ACLR to send out the demand letters?

A I just simply went with expertise of the program office.

Q But not sending out the demand letters was, would be inconsistent with the Part D RAC

contract, correct?

MR. PORADA: Objection.

A If it was in the contract they could do it, but it was program said it wasn't in the best interest to do it, that's all. I don't know what else, what more I could add.

Q Do you know why program office didn't want ACLR to send out demand letters to the plan sponsors?

A I don't know why, but I can tell you we were working really hard to get a revised statement of work in place.

Q Why didn't you just tell ACLR not to issue the demand letters?

A Because it was a part of their statement of work.

Q That they could?

A That they could.

Q What would you have done if ACLR had issued the demand letters?

A I don't know. I don't know.

Q Would you have terminated the ACLR --

A It sounds like it.

Q Do you remember issuing any response to this?

A Maybe a nice thank you, but I don't remember issuing -- I mean, no.

Q Did you ever advise Mr. Mucke that he could execute the contract as it was set forth?

MR. PORADA: Objection to form.

A I don't understand.

Q He writes here, we will continue executing only those portions of the contract that are consistent with current CMS expectations. So CMS had conveyed its expectations of what it wanted under the Part D RAC contract, correct?

A I think we asked Mr. Mucke not to send demand letters and this was just him affirming that he wouldn't and he would wait until he received a revised statement of work from us.

Q And that was what, what you and the program office wanted him to do, correct?

A To not issue demand letters, correct.

Q He says e.g., not issuing demand

July 8, 2011 Emails

EXHIBIT 12

From: Moreno, Cynthia E. (CMS/CPI)
Sent: Friday, July 08, 2011 3:42 PM
To: Yu, Sylvia (CMS/OL); Ozinal, Alper (CMS/OL); James, Merri-Ellen (CMS/CPI)
Subject: RE: Question about Part D RAC
Attachments: PI - Expansion of RACs to Medicare Parts C and D 7 5 11 07 08 11 AO Redline.docx

Here's what I've done so far.

Both Merri-Ellen and Marnie are out this week. I won't be able to complete the response on ACLR's background until later this afternoon. My recollection is that the company doesn't have any experience in healthcare and that it's spent considerable time with tax stuff. I need to find the proposal and see what ACLR wrote.

Cynthia Moreno
410.786.1164

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:

This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

From: Yu, Sylvia (CMS/OL)
Sent: Friday, July 08, 2011 9:15 AM
To: Ozinal, Alper (CMS/OL); Moreno, Cynthia E. (CMS/CPI); James, Merri-Ellen (CMS/CPI)
Subject: RE: Question about Part D RAC

Peter had indicated that the Part D RAC implementation might be a bit tricky to talk about given there will not be any recoupments the first year but it would be good to get a cleared Q&A on what we can say about the Part D RAC since Carper will likely ask at hearing and other staffers will want to know in coming months. I think it's ok to say we are spending the first year making sure the Part D RAC understands the program, the PDE data, and the vulnerabilities in the reinsurance costs. We can say that since this is the first year CMS wants to make sure the RACs are efficient and effective in where they focus their efforts. We just need a few sentences describing what the RAC is doing this first year without highlighting too much the fact that recoupments are being delayed.

From: Ozinal, Alper (CMS/OL)
Sent: Friday, July 08, 2011 8:59 AM
To: Moreno, Cynthia E. (CMS/CPI); James, Merri-Ellen (CMS/CPI)
Cc: Yu, Sylvia (CMS/OL)
Subject: Question about Part D RAC

Hi Cindy/Merri-Ellen,

Thank you for your ongoing help with preparing Peter for his upcoming testimony. Could you take a look at the attached document and let me know if there is anything new to say about the implementation of Part D RACs? I have attached the most recent version of our Q&A, which incorporates your edits and CPC's. We'd appreciate if you could send any edits back by 2 p.m. today. Thanks so much for your help.

--Alper

Alper Ozinal
Centers for Medicare and Medicaid Services
Office of Legislation
Alper.Ozinal@cms.hhs.gov
(202) 205-8028

Expansion of RACs to Medicare Parts C&D
July 5, 2011

Q: What progress has CMS made in implementing the use of RACs in the Medicare Parts C and D programs?[Cindy/Merri-Ellen, please provide update on Implementation of Part D Rac.]

A In January 2011, CMS awarded a contract to identify under and overpayments and recoup overpayments in Medicare Part D. Since contract award, CMS has directed its efforts at ensuring the RAC understands the Part D program, the CMS data security requirements, and the prescription drug event data. The initial audit scope for the RAC is being selected with consideration given to the efficiency and effectiveness of its audit efforts. That means, selecting audit areas that will be readily understood by Part D sponsors and will provide the RAC some immediate successes.

Additionally, we issued a Solicitation for Comment in December 2010 seeking public comment on innovative strategies for review of additional Medicare Parts C and D data, including the effectiveness of sponsors' antifraud plans. While we want to take full advantage of the unique structure of the RAC program, we also want to ensure that we are not duplicating the efforts of other audit initiatives. This approach will maximize the return on investment that the Federal government will receive from contracting with these entities.

Q. For Part C it seems you have missed the December 31, 2010, statutory deadline to implement a RAC, when will you actually have a Part C contract in place? What types of reviews will the Part C RAC do?

A. CMS is currently evaluating the best way to implement a Part C RAC that does not replicate the efforts of ongoing CMS audit initiatives, for example, the risk adjustment data validation audits. CMS is also carefully considering the impact of Part C recovery audits upon providers. This was a theme in the comments CMS received to the solicitation published in December.

Q: Is CMS engaged in other efforts looking at overpayments in the Part C and D program? [Cindy/Merri-Ellen, please provide update on Part D program]

A. Yes. CMS is currently conducting other audits and analyses to identify and collect improper payments in Medicare Part C, including validating risk adjustment data

(RADV) for Medicare Part C payments. RADV is the process used by the CMS to audit the health-status portion of risk-adjusted payments made to Medicare Advantage (MA) organizations. CMS pays Medicare Part C organizations prospectively on a risk-adjusted basis, which takes into account the cost associated with treating individual beneficiaries based on health status. Hence, MA organizations are paid a greater amount to cover sicker beneficiaries. Under RADV, CMS audits medical records from these MA organizations to validate the existence of the diagnoses that lead to the increased Medicare payments that these MA organizations received. If CMS cannot validate these diagnoses in a medical record an overpayment is calculated for the MA organization. The intent of the contract-level RADV audits is to recover improper payments.

CMS is presently conducting RADV audits on 37 MA organizations covering 2007 payment year data.

Q: What company was awarded the Part D RAC contract?

A: ACLR **[Cindy/Merri-Ellen, is there anything more we can say about this? Has ACLR done this work before in the health sector? Or another sector?]**

ACLR is a management consulting firm that specializes in the identification and recovery of overpayments. It's experienced in

Expansion of RACs to Medicare Parts C&D
July 5, 2011

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Q: Is CMS engaged in other efforts looking at overpayments in the Part C and D program? [Cindy/Merri-Ellen, please provide update on Part D program]

A: Yes. CMS is currently conducting other audits and analyses to identify and collect improper payments in Medicare Part C, including validating risk adjustment data

(RADV) for Medicare Part C payments. RADV is the process used by the CMS to audit the health-status portion of risk-adjusted payments made to Medicare Advantage (MA) organizations. CMS pays Medicare Part C organizations prospectively on a risk-adjusted basis, which takes into account the cost associated with treating individual beneficiaries based on health status. Hence, MA organizations are paid a greater amount to cover sicker beneficiaries. Under RADV, CMS audits medical records from these MA organizations to validate the existence of the diagnoses that lead to the increased Medicare payments that these MA organizations received. If CMS cannot validate these diagnoses in a medical record, an overpayment is calculated for the MA organization. The intent of the contract-level RADV audits is to recover improper payments.

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ACLR is a management consulting firm that specializes in the identification and recovery of overpayments. It's experienced in

Excerpts from the Deposition of Marnie Dorsey

EXHIBIT 13

IN THE UNITED STATES COURT

OF FEDERAL CLAIMS

----------x

ACLR, LLC

Plaintiff,

-vs- Civil Action No. 15-767

THE UNITED STATES (Judge Campbell-Smith)

Defendant.

----------x

Wednesday, September 6, 2017

Baltimore, Maryland

THE DEPOSITION OF MARNIE CONNOLLY DORSEY

The deposition of MARNIE CONNOLLY DORSEY was taken on Wednesday, September 6, 2017, commencing at 9:24 a.m., at the Department of Health and Human services, Office of General Counsel, 7500 Security Boulevard, Central Building, Baltimore, Maryland, before CHERYL NICHOLSON, CCR, CLR, Stenotype Reporter and Notary Public in and for the State of Maryland.

something though -- they were getting the data.

Q. Okay. Do you know if they were getting the data from the data storage system?

A. That I don't know.

Q. Okay. Do you know if CMS had established a data storage system for ACLR in connection with the ACLR contract while you were a COTR?

A. I would say no because I don't know for sure.

(Dorsey Exhibit No. 3 was marked for identification.)

BY MR. BONELLO:

Q. I'm showing you what's been marked as Exhibit 3. This is an email dated November 17th, 2010.

You're a recipient on this mail?

A. Yes. Uh-huh.

Q. And does this email pertain to the development of CMS's Part D RAC contract?

A. Yes.

Q. And what's SOO stand for?

Q. -- the IT-SC&A authorization?
A. Yes.
Q. The delay in the issuance of the ATO, that wasn't a result of anything that ACLR did, correct?
A. No. They just didn't have authority to operate within the government.
Q. We just looked at some dates on Exhibit 24.
How come the kickoff meeting for the IT-SC&A wasn't done earlier or the onsite testing done earlier?
A. It had to be scheduled with the contractors or the security.
Q. But was there a way that could have been expedited by you?
A. It actually was expedited. Because we were told that to get an ATO would take upwards of a year, so...
Q. So the ATO was issued on October 7th, 2011, correct?
A. Yes.

A. I don't know.
Q. You don't remember that happening while you were COTR?
A. Them sending false positives?
Q. Correct.
A. I don't know. No. I don't remember them sending the information.
Q. Did ACLR even submit any overpayments to CMS while you were COTR?
A. No. I don't believe so.
Q. And in 2011 did the data validation contractor identify any instances where ACLR incorrectly identified an overpayment?
A. While I was there, no, because there hadn't been anything done yet.
Q. Did CMS provide the data validation contractor with any ACLR overpayment determinations?
A. No. I don't think so.
Q. Do you recall a meeting of November 20th, 2011 between you and Mr. Mucke, Tanette Downs, Wheeler and Jessica Sanders?

A. Do I recall it?
Q. Yes.
A. No. But, you know, it's been a while.
Q. And do you recall that November 20th of 2011 you believed that the performance work statement of ACLR's was simply a proposal?
A. I don't think it was approved by that time, no.
Q. The performance work statement wasn't approved by CMS.
A. No.
Q. Is that your position?
A. Uh-huh. Yes.
Q. It was not?
A. It was not.
Q. So CMS did not have an obligation to file the performance work statement?
A. Did they have the obligation?
Q. Did CMS have an obligation to allow ACLR to comply with the performance work statement?
MR. PORADA: Objection.

THE WITNESS: That would be an OAGM question.

BY MR. BONELLO:

Q. You're the COTR on the contract but --

A. I'm just -- yeah. But I'm only -- OAGM makes the decisions contract-wise.

Q. But it was your position in November of 2011 that the performance work statement was merely a proposal, correct?

A. I'm sorry. I lost what you said at the end.

Q. In November 2011 it was your position that the performance work statement of ACLR's was simply a proposal. Isn't that true?

A. Yes.

Q. And that it needed to be changed?

A. It hadn't been blessed yet from management. So there were changes still being made to it, I believe, yes.

Q. And that was the opinion of the team assigned to implementing the Part D RAC?

A. Which team?

Q. Your team.
A. Yes.
Q. Was that, again, the performance work statement, which is contained in Exhibit 15, was simply a proposal. Is that true?
A. Yes. It hadn't been fully vetted, so yes.
Q. And you conveyed that belief to Chris Mucke at ACLR?
A. Yeah, I guess. I don't -- I can't remember that meeting, but, yeah, I guess.
Q. Was the perspective that the performance work statement included in Exhibit 15 was just a proposal one of the reasons that Booz Allen was contracted to develop the statement of work for the Part D RAC?
MR. PORADA: Objection to form.
THE WITNESS: I don't know. I don't know. I know they were working on a statement of work.
BY MR. BONELLO:

little confusion. This is Jessica. I'm sorry. I was the contract...)

BY MR. BONELLO:

Q. Okay. I'm finished with the recording.

Were you making a statement in the recording that we played?

A. Did I make statement -- yes --

Q. Yes.

A. -- about the performance work statement?

Q. Yes.

A. Yes.

Q. And that was your voice --

A. Yes.

Q. -- in the recording?

A. Uh-huh.

Q. Do you recall the meeting or the conversation?

A. I don't recall the meeting per se, but that is me and I was saying that the key -- the PWS was sent from ACLR but that it hadn't been

approved per se.

So we were still working on finalizing everything else to go with that. So it just says the performance work statement was not contractual.

Q. And who else was speaking in that recording, then, to the best of your recollection, besides yourself?

A. It sounded like Tanette Downs. It sounded like Desiree Wheeler -- I think that's her last name -- and then Jessica was the contracting specialist. I think her last name is Sanders. I think.

Q. And we had this meeting as from November 2011. Is that consistent with your recollection of when it might have taken place?

A. I'm assuming. I don't -- it's hard to like go back that many years, but yeah.

MR. BONELLO: All right. Off the record. (Off the record.)

(Whereupon, at 1:45 p.m., the taking of the deposition concluded.)

October 7, 2011 Authorization Decision

EXHIBIT 14

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N3-15-25
Baltimore, Maryland 21244-1850

CENTERS for MEDICARE & MEDICAID SERVICES

OFFICE OF INFORMATION SERVICES

MEMORANDUM

DATE: OCT - 7 2011

TO: Director
Medicare Program Integrity Group (MPIG)

FROM: Chief Information Officer, and
Director, Office of Information Services (OIS)

SUBJECT: Authorization Decision for Recovery Audit Contractor Part D ACLR (RAC Part D ACLR)

ACTION REQUIRED 30 DAYS FROM THE DATE OF THIS MEMORANDUM

The Recovery Audit Contractor Part D ACLR (RAC Part D ACLR) system is a *Moderate* system located at a co-location data in Atlanta, Georgia. The business function for which ACLR was contracted is to retrieve Medicare Part D prescription drug event data for audit and recovery of improper payments.

On September 1, 2011, you certified the controls for the system and submitted along with your certification the other required documentation to obtain an authority to operate for the RAC Part D ACLR. However, the most recent Security Assessment has indicated that there is an overall higher volume of *moderate* and *low* risk findings than are typical for comparable CMS systems. These aggregate findings present an overall higher risk than is typical for this class of system.

Therefore, I have determined, through a thorough review of the authorization package that the risk to CMS information and information systems resulting from the operation of RAC Part D ACLR is acceptable predicated on the completion of the actions described in the attachment. Accordingly, **I am issuing an Authorization to Operate (ATO)** for RAC Part D ACLR to operate in its current environment and configuration until **October 15, 2012**. This ATO allows sufficient time to lower the overall risk of the system by closing the large number of open findings.

This security authorization decision is my formal declaration that adequate security controls have been implemented in the information system and that a satisfactory level of security is present in the system. The security authorization of the information system will remain in effect as long as: (i) the required security status reports for the system are submitted to this office in accordance with current CMS policy; (ii) the vulnerabilities reported during the continuous monitoring process do not result in additional agency-level risk that is deemed unacceptable; and (iii) the system has not exceeded the maximum allowable time period between security authorizations in accordance with Federal or CMS policy.

The attachment provides information on requirements not met, as well as corrective actions needed to bring them into compliance. The actions set forth in the attachment must be entered

Attachment

Recovery Audit Contractor Part D ACLR (RAC Part D ACLR)

Authorization Decision

Authorization decision is required for the following reason(s):

X	New System
	Major system modification
	Serious security violation
	Changes in the threat environment
	Expired authorization to operate

I. Authorization Decision

I have reviewed the information concerning the request for an Authorization to Operate and, with consideration of the recommendations provided by my staff; I concur with the assessment of the security risk. This risk has been weighed against the business operational requirements and security measures that have or will be implemented. I have determined the following authorization decision is appropriate.

X	**Authorization to Operate** The current risk is deemed to be acceptable. The applicable system is authorized to operate until the designated date, subject to the authorization actions in Section II.
	Interim Authorization to Operate The current risk is deemed to be higher than desired. The applicable system may operate for a limited period without authorization until the designated date, subject to completion of authorization actions in Section II, after which, verification and resubmission of the authorization package is required.
This authorization will expire on: October 15, 2012. This authorization may be withdrawn at the discretion of the Authorizing Official for lack of progress on the authorization actions in Section II, or any security violations deemed to increase the risk to CMS beyond a tolerable level.	

	Denial of Authorization to Operate The current risk is deemed to be unacceptable. The applicable system may not operate until the authorization actions listed in Section II are completed, after which, verification of corrective actions and resubmission of the authorization package is required.

(Authorizing Official Signature and Date)
Tony Trenkle
CMS Chief Information Officer

Recovery Audit Contractor Part D ACLR (RAC Part D ACLR)

II. Authorization Actions

Failure to meet the assigned due dates without prior approval invalidates this authorization to operate. The following specific actions are to be completed by the date(s) indicated:

Vulnerability	Control/Action Description	Due Date
The Privacy Impact Assessment (PIA) has not been vetted through or signed by the CMS Privacy Office.	Vet the PIA document, obtain a CMS Privacy Officer's signature, and post the PIA document in CFACTS.	January 9, 2012
Information in CFACTS is inconsistent or missing.	Update contacts in CFACTS to reflect current CMS positions. Include the identification section, security controls tab, interconnections section, inventory (including Systems), and consider ISAs with external entities.	January 9, 2012
The System Security Plan (SSP) is incomplete.	SSP must be updated to include the description of the business process, operational information, system information, and the system environment.	January 9, 2012

Attachment

Recovery Audit Contractor Part D ACLR (RAC Part D ACLR)

Vulnerability	Control/Action Description	Due Date
There are an excessive number of open medium risk findings.	Even though there are no high risk findings, there are an excessive number of open findings, presenting an excessive aggregate risk to sensitive information being processed on behalf of CMS. The following open findings, along with the applicable non-compliant CMS minimum security requirements, are: • RAC Part D ACLR_D_2011_2 - AC-6 Least Privilege, • RAC Part D ACLR_D_2011_3 CM-7 Least Functionality, • RAC Part D ACLR D_2011_4 - CM-7 Least Functionality, • RAC Part D ACLR_D_2011_5 - SC-13 Use of Cryptography, • RAC Part D ACLR_D_2011_6 - SC-13 Use of Cryptography, • RAC Part D ACLR_D_2011_8 - CP-2 Contingency Plan, • RAC Part D ACLR_D_2011_9 - RA-3 Risk Assessment, • RAC Part D ACLR_D_2011_10 - AC-4 Information Flow Enforcement, • RAC Part D ACLR_D_2011_11 - AC-3 Access Enforcement, • RAC Part D ACLR_D_2011_12 - AC-5 Separation of Duties, • RAC Part D ACLR D 2011_13 - PL-2 System Security Plan (SSP), • RAC Part D ACLR_D_2011_14 - SA-3 Life Cycle Support, • RAC Part D ACLR_D_2011_15 - PE-2 Physical Access Authorizations, PE-6 Monitoring Physical Access, • RAC Part D ACLR_D_2011_16 - SI-2 Flaw Remediation, • RAC Part D ACLR_D_2011_17 - Access Control, • RAC Part D ACLR_D_2011_18 - AU-6 Audit Review, Analysis, and Reporting, and • RAC Part D ACLR D_2011_20 - AC-2 Account Management. The action is to close the open findings and become compliant with the applicable CMS minimum security requirements.	June 15, 2012
END OF ACTIONS		

GAO Report, MEDICARE PART D: Changes Needed to Improve CMS's Recovery Audit Program Operations and Contractor Oversight

EXHIBIT 15

United States Government Accountability Office

Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

August 2015

MEDICARE PART D

Changes Needed to Improve CMS's Recovery Audit Program Operations and Contractor Oversight

August 2015

MEDICARE PART D

Changes Needed to Improve CMS's Recovery Audit Program Operations and Contractor Oversight

GAO Highlights

Highlights of GAO-15-633, a report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

In 2014, the federal government spent $58 billion on Medicare Part D, the voluntary, outpatient prescription drug coverage program. An estimated $1.9 billion of this total was improper payments—including overpayments or underpayments that may be due to errors, such as the submission of duplicate claims for the same service. In January 2011, CMS began a RAC program in Part D that was intended in part to identify and recoup improper payments, as required under the Patient Protection and Affordable Care Act. The RAC is paid a contingency fee from amounts recovered.

GAO was asked to review CMS's Part D RAC program implementation, oversight, and results. GAO examined (1) how CMS has implemented the Part D RAC program and any challenges it faced during implementation; (2) the extent to which CMS has overseen the RAC's audit activities, and (3) the results of the RAC's work to date and any challenges CMS and the RAC faced in identifying and collecting improper payments. To do this, GAO analyzed the RAC contract and audit documents, and federal statutes and regulations on Part D and federal contracting. GAO also interviewed CMS and RAC officials.

What GAO Recommends

As CMS prepares to solicit the next RAC contract(s), CMS should set clear expectations in contract work statements, conduct annual RAC performance evaluations, and review the process for developing new audit issues. HHS concurred with GAO's recommendations.

View GAO-15-633. For more information, contact Kathleen King at (202) 512-7114 or kingk@gao.gov.

What GAO Found

The Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS) implemented the Part D recovery audit contractor (RAC) program in January 2011 by undertaking various activities, including establishing a statement of objectives and conducting a solicitation process to select a RAC to identify improper payments. However, CMS's challenges in setting expectations about the work the Part D RAC would conduct and establishing the length of time required for CMS and the RAC to reach project milestones hampered Part D RAC program implementation. Consistent with federal contracting requirements, agencies should clearly define requirements for services. As a result of CMS's challenges in setting expectations and establishing realistic timelines as it implemented the RAC program, the RAC did not have a clear understanding about the work it should perform, and CMS recovered improper payments for Part D more than a year after it had projected.

As of May 2015, CMS had not completed any annual evaluations of the Part D RAC, but an initial evaluation of the RAC's contract year 2014 performance was in progress, and the agency had conducted other oversight of the RAC's performance. Federal internal controls and contracting standards and GAO's prior work contain requirements and suggestions for conducting regular performance evaluations and developing performance measures. In March 2015, CMS officials acknowledged that the agency should have completed annual evaluations and noted that CMS has been behind schedule in conducting evaluations of some its contractors, including the RAC. In May 2015, CMS officials finished the initial evaluation of the RAC's 2014 performance and provided the evaluation to the RAC for review and comment. An annual performance evaluation would provide CMS with a clear basis for assessing RAC performance in identifying improper payments and provide the RAC with targets against which the RAC could compare its performance. While CMS has not completed annual evaluations, it has established quality assurance procedures to conduct oversight of the RAC. For example, CMS uses a separate contractor to review and validate 100 percent of the RAC's audit findings, in part because of concerns about the quality of the RAC's work.

As of May 2015, CMS had collected less than $10 million in improper payments, and had not approved the RAC to perform new audit work since March 2014. Both CMS and the RAC are charged with reducing Medicare Part D improper payments, and federal internal control standards call for agencies to have effective and efficient processes to meet agency goals. However, as a result of CMS's and the RAC's challenges in determining audit work to conduct and the RAC's challenges in developing audit methodologies, CMS has approved 1 of the 15 audit proposals from the RAC since the beginning of the contract in 2011 and has collected a limited amount of improper payments relative to the estimated $1.9 billion in improper payments in Part D in 2014. With a more effective and efficient process for identifying, reviewing, and approving appropriate new audit work, more audit work would likely have been approved each year of the RAC contract, resulting in more improper payments being identified and collected.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
FAR	Federal Acquisition Regulation
HHS	Department of Health and Human Services
PDE	prescription drug event
PPACA	Patient Protection and Affordable Care Act
RAC	recovery audit contractor

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE

August 14, 2015

The Honorable Kevin Brady
Chairman
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

In 2014, the federal government made an estimated $1.9 billion in improper payments for the Medicare Part D prescription drug program—about 3.3 percent of the $58 billion spent for Part D that year.[1] Improper payments include overpayments or underpayments that may be due to errors, such as the inadvertent submission of duplicate claims for the same service.[2] Since billions of dollars are estimated to be paid in error annually, the Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services (HHS) that is responsible for managing and overseeing the Part D program, conducts a number of activities to address improper payments, including post-payment reviews of claims potentially paid in error.[3] The Tax Relief and Health Care Act of 2006 required CMS to implement a national Medicare recovery audit contractor (RAC) program in Medicare's fee-for-service

[1]Medicare is the federally financed health insurance program for persons aged 65 and over, certain individuals with disabilities, and individuals with end-stage renal disease. Part D provides voluntary outpatient prescription drug coverage for eligible individuals 65 years and older and eligible individuals with disabilities.

[2]An overpayment is a payment that should not have been made or was higher than allowed. An underpayment is a payment that should have been made, but was not, or was lower than allowed. For purposes of this report, we refer to overpayments and underpayments as improper payments. Improper payments may also be a result of misconduct, such as fraud; however, for this report, we are not examining the potential for fraud within Medicare Part D.

[3]Because of Medicare's susceptibility to improper payments, as well as its size and complexity, for more than 20 years we have designated Medicare as a high-risk program. See GAO, *High-Risk Series: An Update*, GAO-15-290 (Washington, D.C.: February 2015).

programs to increase efforts to identify and recoup improper payments.[4] The Patient Protection and Affordable Care Act (PPACA) expanded the RAC program to Part D, and required CMS to enter into a Part D RAC contract by December 31, 2010, among other things.[5] CMS awarded a contract to a Part D RAC to carry out recovery audit activities in January 2011.

In light of Medicare Part D's susceptibility to improper payments and the PPACA requirement to extend recovery audit activities to the Part D program, you asked us to study CMS's RAC program implementation, oversight, and results. This report examines (1) how CMS has implemented the Medicare Part D RAC program, and what, if any, challenges CMS has faced during its implementation; (2) the extent to which CMS has conducted oversight of the Medicare Part D RAC; and (3) the results of the RAC's audit work to date, and what, if any, challenges CMS and the RAC have faced in identifying potential improper payments.

To determine how CMS has implemented the Medicare Part D RAC program and what, if any, challenges CMS has faced during its implementation, we analyzed PPACA requirements and CMS rules and federal notices to identify requirements for the Part D RAC program. We reviewed relevant CMS documents, including CMS's statement of objectives for the Part D RAC program and the RAC contract and its subsequent modifications, to examine the policies and guidance CMS established to implement the RAC program. We also reviewed relevant documents created by the Part D RAC and incorporated into its contract, including its performance work statement, which outlines how the RAC planned to conduct its work, and its implementation timeline. In addition, we reviewed relevant Federal Acquisition Regulation (FAR) provisions

[4]Pub. L. No. 109-432, div. B, title III, § 302, 120 Stat. 2922, 2991-92 (codified at 42 U.S.C. § 1395ddd(h)). Prior to the Tax Relief and Health Care Act of 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed CMS to conduct a 3-year demonstration project on the use of RACs to identify improper payments. Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256-57.

[5]Pub. L. No. 111-148, § 6411(b), 124 Stat. 119, 775 (2010) (codified at 42 U.S.C. § 1395ddd(h)). PPACA required the expansion of the RAC program from Medicare Part A and Part B—Medicare's fee-for-service programs—to Medicare Part C, under which beneficiaries receive benefits through private health plans, and Part D. Since 2009, CMS has contracted with RACs in a national program to identify improper payments in Medicare fee-for-service programs.

and our prior work regarding clearly defining requirements and managing change for projects and compared implementation activities to the FAR requirements and our prior work.[6] We interviewed CMS officials from the Center for Program Integrity, Center for Medicare, and Office of Acquisition and Grants Management and RAC officials regarding CMS's implementation of the Part D RAC program, including challenges CMS faced during its implementation.

To determine the extent to which CMS has conducted oversight of the Medicare Part D RAC, we analyzed contract documents to determine whether CMS had set a performance evaluation schedule and performance standards for the RAC. We also reviewed CMS documentation for evaluations and other oversight conducted by CMS. We interviewed the CMS and RAC officials regarding CMS oversight of the RAC. In addition, we compared CMS's oversight activities to criteria on performance assessment, such as those outlined in federal internal control standards, applicable FAR provisions, and our prior work.[7]

To determine the results of the RAC's audit work to date and what, if any, challenges CMS and the RAC have faced in identifying potential improper payments, we reviewed the contract documents and other CMS documents related to the RAC work CMS requested, and the processes the RAC was required to follow to conduct its audit work. We analyzed data we received from the RAC on proposed audit work submitted to

[6]The FAR establishes uniform policies and procedures used by federal executive branch agencies for their acquisitions of supplies and services. 48 C.F.R. ch. 1. We reviewed relevant FAR requirements and our prior reports related to service contracting, in particular the management of service contracts and performance-based acquisitions. See 48 C.F.R. part 37. See also GAO, *Acquisition Planning: Opportunities to Build Strong Foundations for Better Services Contracts*, GAO-11-672 (Washington, D.C., Aug. 9, 2011), and *Defense Acquisitions: Stronger Management Practices Are Needed to Improve DOD's Software-Intensive Weapon Acquisitions*, GAO-04-393 (Washington, D.C., Mar. 1, 2004).

[7]See 48 C.F.R. part 37. See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C., November 1999), *Internal Control Management and Evaluation Tool*, GAO-01-1008G (Washington, D.C., August 2001), *Performance Measurement and Evaluation: Definitions and Relationships*, GAO-11-646SP (Washington, D.C., May 2011), and *National Preparedness: Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals*, GAO-13-278 (Washington, D.C., March 2013). Control activities refer to an agency's ability to ensure that its policies and procedures enforce management's directives.

CMS for approval, CMS's decision notices on proposed work, and, for approved work, data on the amounts of improper payments identified and the amounts recouped. We determined that these data were sufficiently reliable for our purposes by confirming and clarifying information provided by the RAC with CMS officials. We also reviewed records of communications between the RAC and CMS and interviewed RAC and CMS officials to determine what, if any, challenges the RAC and CMS have faced in identifying potential overpayments and underpayments. In addition, we reviewed CMS's strategic plan and the RAC's statement of objectives and compared RAC program results and activities to these goals and objectives.

We conducted this performance audit from September 2014 to August 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Since 2006, CMS has contracted with private companies, referred to as plan sponsors, to provide outpatient prescription drug plans for Medicare beneficiaries.[8] In 2014, there were 3,455 prescription drug plans offered nationwide.[9] Every time a Medicare beneficiary fills a prescription covered under Part D, the sponsor must submit a prescription drug event (PDE) record to CMS. These records include drug cost and payment information that enables CMS to administer and monitor the Part D benefit. Plan

[8]Throughout this report, we use the terms "Part D prescription drug plans" and "Part D plans" interchangeably to refer to these plans.

[9]Beneficiaries may choose Part D plans from among multiple plans offered by Part D plan sponsors that contract with CMS. Part D plan sponsors may have multiple contracts with CMS to provide drug coverage, with each contract covering one or more distinct Part D plans.

sponsors are required to have comprehensive compliance programs that include a plan to safeguard the program from fraud, waste, and abuse.[10]

Medicare Part D Benefit and Payment Structure

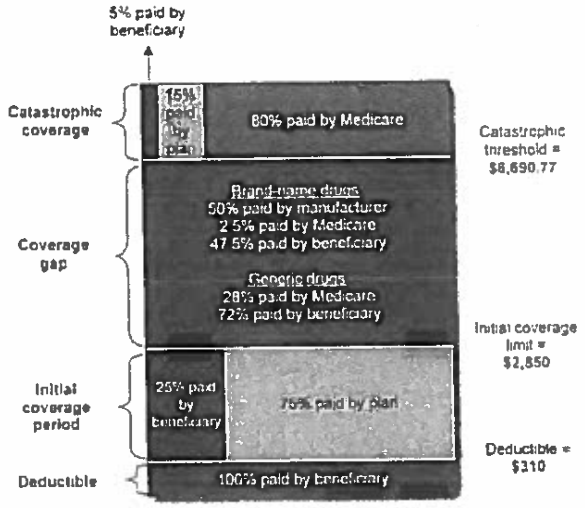
Plan sponsors are required to offer plans that provide a minimum set of benefits to beneficiaries—the standard benefit—or an actuarially equivalent benefit.[11] Beneficiaries pay monthly premiums and cost sharing—such as coinsurance—for drug purchases. The amount of cost sharing varies over the course of the year as beneficiaries move through the phases of the benefit. As shown in figure 1, the standard benefit in 2014 featured a $310 deductible and an initial coverage period during which beneficiaries pay coinsurance of 25 percent of the cost for prescription drugs until they reach the initial coverage limit of $2,850. After the initial coverage period, beneficiaries enter a coverage gap, during which beneficiaries pay a large share of drug costs.[12] After reaching the catastrophic threshold, beneficiaries pay a small share of total drug costs. Under Part D, certain individuals are also entitled to a low-income subsidy, through which they pay reduced premiums and generally have zero or nominal cost sharing.

[10]The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 which established the Part D program, requires all Part D sponsors to have programs to safeguard Part D from fraud, waste, and abuse. Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2086 (codified at 42 U.S.C. § 1395w-104(c)(1)(D)). CMS issued regulations requiring that sponsors adopt and implement a compliance program that includes measures to prevent, detect, and correct fraud, waste, and abuse. 42 C.F.R. § 423.504(b)(4)(vi).

[11]To provide an actuarially equivalent benefit—a set of benefits different from the standard minimum benefits, but of equal value—plan sponsors must meet certain requirements, including obtaining the approval of CMS.

[12]PPACA included provisions that phase out this coverage gap by 2020. Beneficiary cost sharing under the standard benefit will be reduced gradually until 2020, when the coverage gap will be eliminated. Once the coverage gap is phased out, beneficiaries will pay 25 percent cost sharing for all drugs until they reach the catastrophic threshold. See Pub. L. No. 111-148, § 3301, 124 Stat. 119, 461, (2010), as amended by Pub. L. No. 111-152, § 1101, 124 Stat. 1029, 1036 (2010) (codified at 42 U.S.C. §§ 1395w-101 et seq.).

Figure 1: Medicare Part D Cost-Sharing Structure under the Standard Benefit, 2014



Source: GAO analysis of CMS information. | GAO-15-833

Note: Plan sponsors are required to offer plans that provide a minimum set of benefits to beneficiaries—the standard benefit—or an actuarially equivalent benefit. The cost-sharing structure under the standard benefit does not apply to beneficiaries who receive the Part D low-income subsidy, who generally have zero or nominal cost-sharing.

In addition to the subsidy for certain low-income individuals, Medicare also provides Part D plans with direct subsidy payments and reinsurance payments. The direct subsidy is a monthly prospective capitated payment to plans adjusted for the health status of beneficiaries expected to enroll, among other things. Reinsurance payments are monthly subsidies Medicare pays to plans that cover 80 percent of plans' estimates for beneficiaries that incur costs above the catastrophic threshold.[13]

CMS Oversight of Part D

CMS has a goal to reduce improper payments in the Medicare Part D program and conducts a number of activities to protect the integrity of the program—that is, to ensure that payments are made correctly the first

[13]In addition, Medicare establishes risk corridors for each plan, which is a risk-sharing mechanism by which CMS finances higher-than-expected costs and recoups excessive profits.

time and to identify, investigate, and recoup payments made in error.[14] CMS's Center for Program Integrity oversees Part D program integrity. Within the Center for Program Integrity, the Division of Plan Oversight and Accountability is responsible for administering the Part D RAC program. The Division of Plan Oversight and Accountability coordinates its efforts with components in CMS's Center for Medicare and the Office of Acquisition and Grants Management.

Part D RAC Program

The Part D RAC is required under PPACA to conduct post-payment reviews to identify improper payments in the Part D program. In addition, the RAC is required to conduct three additional activities:

- ensure that each Part D prescription drug plan has an antifraud plan in effect and review the effectiveness of each plan;
- examine Part D prescription drug plans' claims for reinsurance payments to determine whether costs were incurred in excess of the costs allowed; and
- review Part D prescription drug plans' estimates for the enrollment of high-cost beneficiaries and compare to the numbers of high-cost beneficiaries actually enrolled.

The RAC uses a CMS-approved audit methodology to identify potential improper payments, takes steps to have its work validated by another contractor, and provides plan sponsors with an opportunity to appeal its findings, prior to CMS collecting any confirmed improper payments. The RAC may use data from CMS and the HHS Office of Inspector General, such as CMS's Medicare Exclusion Database or the Office of Inspector General's List of Excluded Individuals/ Entities, among other sources, and compare those data to Medicare Part D claims data that plan sponsors submit in PDE records to identify potential improper payments.[15] The

[14]This goal is part of HHS's Strategic Plan for fiscal years 2014 through 2018. See Department of Health and Human Services, *Fiscal Year 2016 Annual Performance Plan and Report* (Washington, D.C., February 2015.)

[15]The Office of Inspector General's List of Excluded Individuals/ Entities includes all individuals and entities currently excluded from participating in federally funded health care programs, including Medicare and Medicaid. Exclusions are imposed for a number of reasons, such as Medicare fraud or patient abuse or neglect. The Medicare Exclusion Database contains information on provider exclusions—including the information from the Office of Inspector General's List of Excluded Individuals/ Entities—sanctions and reinstatements in a standard, cumulative format with monthly updates.

RAC reviews all contracts that fall within a particular year for a particular plan sponsor unless directed to do otherwise by CMS, and may identify potential improper payments on PDE records within 4 years of the plan sponsor's current plan year.[16] After the RAC has identified potential improper payments in PDE records, a data validation contractor confirms the results and works with the RAC to resolve any discrepancies, for example in the amount of improper payments identified or the number of PDE records containing potential improper payments. Once the RAC's results are finalized, the results are sent to the plan sponsor to give it an opportunity to appeal the RAC's results, that is, to request a reconsideration of the identified potential improper payments and provide additional documentation to support its request. After all appeals are considered and final decisions are made, CMS collects improper payments from plan sponsors. The RAC is paid on a contingency fee basis from amounts recovered, as required by law.[17] This payment is a percentage of the improper payments that CMS collects after the appeals process has been completed.

CMS Undertook Various Activities to Establish the Part D RAC Program, but Unclear Expectations and Unrealistic Project Timelines Hampered Implementation

CMS implemented the Part D RAC program in January 2011 by undertaking various activities, including establishing a statement of objectives and conducting a solicitation process to select a RAC to identify improper payments. CMS officials told us the agency addresses additional PPACA requirements for the Part D RAC program through other activities it conducts. However, unclear expectations about the work the Part D RAC would conduct and unrealistic timelines regarding project milestones hampered Part D RAC program implementation.

[16]A plan sponsor may have more than one Part D contract at any one time.

[17]See 42 U.S.C. § 1395ddd(h)(1)(A)-(B).

CMS Implemented the Part D RAC Program by Establishing a Statement of Objectives and Conducting a Solicitation Process to Select a Contractor

CMS implemented the Part D RAC program in January 2011 by undertaking various activities, such as establishing a statement of objectives, conducting a solicitation process to select a contractor, and awarding a Part D RAC contract. CMS's statement of objectives described the outcomes that CMS required a Part D RAC to achieve, such as developing a methodology to identify improper payments. Prospective contractors were to use this statement of objectives to design a performance work statement to describe how they would conduct their work to achieve those objectives.[18] According to CMS officials, the majority of CMS contracts include a statement of work that describes how contractors should conduct their work. However, CMS officials decided that prospective contractors for the Part D RAC program would design their own performance work statements instead because CMS officials said they wanted to give industry the opportunity to shape the program.

After CMS created the statement of objectives, it solicited contractors to serve as the Part D RAC using the General Services Administration's Federal Supply Schedule.[19] Although using the Federal Supply Schedule limited the number of potential contractors that could respond to CMS's solicitation and from which CMS could choose, CMS officials said the agency chose this solicitation method because it was a streamlined approach to generate interest from contractors already approved to work for the federal government. According to CMS officials, CMS received two proposals from potential contractors, and only one of them was found to be technically acceptable. CMS officials said that they reviewed the potential contractors' performance work statement and assessed their experience with Medicare Part D and knowledge of Medicare Part D statutes and regulations, along with other qualifications. CMS selected the only contractor whose proposal, including its performance work statement, the agency considered technically acceptable. While this

[18]CMS officials said they selected a performance-based contract type permissible under the FAR for the Part D RAC contract. Agencies should, to the extent possible, acquire services using performance-based acquisitions. 48 C.F.R. § 37.102. These contracts are to include a performance work statement, which may be prepared by the prospective contractor based on a statement of objectives provided by the agency. 48 C.F.R. §§ 37.601(b)(1), 37.602(a).

[19]The Federal Supply Schedule provides federal agencies with a simplified process for obtaining commercial supplies and services at prices associated with volume buying. See 48 C.F.R. § 8.402. Use of the Federal Supply Schedule fulfills the requirement for full and open competition, and agencies may not seek competition outside of the Federal Supply Schedule when using this procedure. 48 C.F.R. §§ 6.102(d)(3), 8.404(a).

contractor did not have any previous federal experience, CMS determined that its recovery audit experience in the private sector was sufficient. In January 2011, when CMS awarded a contract to the contractor selected to serve as the Part D RAC, the contractor's performance work statement became part of the contract. As such, the performance work statement established requirements and set expectations for the work the RAC would perform and how the work would be conducted.

The RAC's initial contract period was for 1 base year with four 1-year options for extension, although CMS extended the base period of the contract eight times over a 2-year period through contract modifications.[20] The base period was originally through January 2012; however, it was extended through December 2013. At that time, CMS and the RAC agreed in a contract modification to revise the performance period to reflect a 3-year base period, two 12-month option periods, and a separate nearly 13-month option for administrative and appeals activities. CMS and the RAC exercised the first option period of the modified contract, which ran from January through December 2014, and then the second and final option period, which ends December 31, 2015.[21]

CMS officials said they plan to obtain the RAC services on the open market using a full and open competitive solicitation and select a contractor to begin serving as the Part D RAC under new contract terms in January 2016. CMS officials also said the 2016 Part D RAC contract will include a statement of work.

CMS Said It Implemented Three Additional PPACA Requirements for the Part D RAC Program

According to CMS officials, the RAC cannot perform activities to address the three additional PPACA requirements for the Part D RAC program, and therefore CMS conducts activities that address these requirements. CMS officials told us that the RAC cannot perform activities to address the additional requirements because the fee that CMS is statutorily required to pay the RAC is based on improper payments identified by the

[20]CMS made the first extension in January 2012 and the last in November 2013.

[21]The nearly 13-month option for administrative and appeals activities runs from January 1, 2016, through January 24, 2017.

RAC, and there is no allowance under the statute for payment for other work done by the RAC.[22]

However, CMS conducts certain activities that, according to CMS officials, address the three PPACA requirements:

- *Ensure that each Part D plan has an antifraud plan in effect and review the effectiveness of each plan*—According to CMS officials, the agency meets this requirement by conducting program compliance audits of plan sponsors, which include a review of the sponsors' antifraud plans. According to CMS officials, 96 percent of beneficiaries are enrolled in Part D plans that have been reviewed within a 5-year period as part of these compliance audits. In addition, CMS conducted a pilot study from September 2013 to February 2014 to review the effectiveness of five plan sponsors' antifraud plans. CMS officials said the findings from this study will be used to inform and, if necessary, improve CMS's reviews of sponsors' antifraud plans as part of its compliance audits.
- *Examine Part D plans' claims for reinsurance payments to determine whether costs were incurred in excess of the reinsurance costs allowed*—According to CMS officials, the agency meets this requirement through its reconciliation of Part D plans' reinsurance estimates to their actual costs.[23] As CMS has noted, Part D plans legitimately incur costs in excess of allowable reinsurance costs during the catastrophic coverage period of the Part D benefit.[24] CMS pays prospective reinsurance payments to Part D plans, based on the plans' estimates of reinsurance costs, and reconciles these prospective reinsurance payments to the plans' actual reinsurance costs on an annual basis.

[22]See 42 U.S.C. § 1395ddd(h)(1)(A).

[23]CMS makes reinsurance payments to Part D plans on a monthly basis throughout the calendar year, based on plans' estimates for beneficiaries that incur costs above the catastrophic coverage limit for Part D. At the end of the calendar year, CMS reconciles these prospective reinsurance payments to the actual incurred costs, net of any direct or indirect remuneration and other related data, and makes appropriate adjustments to the plan payments.

[24]75 Fed. Reg. 81,278, 81,280 (Dec. 27, 2010).

- *Review Part D plans' estimates for the enrollment of high-cost beneficiaries and compare to the numbers of high-cost beneficiaries actually enrolled*—According to CMS officials, the agency meets this requirement through its reconciliation of Part D plans' reinsurance estimates to their actual costs. These officials said that although Part D plans do not submit actual estimates for the enrollment of high-cost beneficiaries to CMS, the plans' estimates of the number of beneficiaries who will reach the catastrophic threshold affect plans' reinsurance estimates, which are examined as part of the reconciliation process, as noted above.

Unclear Expectations and Unrealistic Project Timelines Hampered RAC Program Implementation

CMS's challenges in setting expectations about the work the Part D RAC would conduct and establishing the length of time required for CMS and the RAC to reach project milestones hampered Part D RAC program implementation. CMS's expectations for the work the RAC would perform were unclear because although CMS incorporated the terms of work set out in the performance work statement into the RAC's contract without making any changes to the performance work statement, CMS later proposed audit work for the RAC to pursue that differed from the work described in the performance work statement. For example, the initial RAC audit process outlined in the performance work statement broadly focused on reviews of all PDE records to eliminate duplicate payments, to validate the accuracy of information in required PDE data fields and edit checks, and to validate the information in direct and indirect remuneration reports and PDE records by comparing it to additional documentation received from the plan sponsors.[25] However, CMS officials proposed that the RAC focus its initial audit work only on providers that were excluded from the Medicare program yet had written or filled prescriptions that were paid for by CMS, and this became part of a contract modification in February 2012.[26] A senior official with the RAC said that the RAC

[25]Sponsors provide CMS with information about the rebates they receive in reports known as direct and indirect remuneration reports. During the reconciliation process, CMS uses the information in these reports to compare the sponsors' costs to the prospective monthly payments sponsors received from CMS and the premiums they charged beneficiaries. In July 2014, the RAC withdrew its proposal to conduct an audit of direct and indirect remuneration reports after CMS recommended the audit issue be limited to a pilot. A senior RAC official said that a contract modification would have been necessary to conduct the pilot, and one was not agreed to.

[26]Excluded providers are providers who are ineligible to receive Medicare funds for various reasons, such as having been convicted of a felony relating to health care fraud.

expected to conduct the audit process described in its performance work statement and did not learn until after the first contract year that the initial audit work would be narrowly scoped and proposed by CMS.

In addition, CMS required the RAC to follow processes for determining audit work and validating audit findings that differed from the processes set out in the performance work statement. For example, after CMS selected the initial audit work the RAC would conduct, CMS required the RAC to obtain CMS approval before it began work on subsequent audits. CMS also required a data validation contractor to review and validate the RAC audit findings.[27] However, these steps were not included in the processes outlined in the performance work statement, and a senior official with the RAC said the RAC did not learn that CMS had adopted processes that required these steps until the end of the first contract year. The senior official with the RAC said the additional steps significantly lengthened the time it took to select audit topics and conduct audits, and reduced the number of audits the RAC was able to perform.

CMS officials said they proposed that the RAC perform work and follow processes that were not in the performance work statement because they recognized during the first year of the contract that the RAC had less expertise in Medicare Part D regulations and the Part D benefit than was necessary. For example, CMS officials said that the RAC required significant assistance in developing its audit methodology because it lacked staff with adequate knowledge of Medicare Part D. According to these officials, in some cases it was necessary for CMS to develop audit methodology on the RAC's behalf, and in other cases, CMS needed to revise the RAC's methodology to eliminate numerous false positives—payments that the RAC incorrectly determined were overpayments—identified by the data validation contractor. CMS officials also said that they incorporated into the audit work CMS guidance, policies, and other internal processes in order to help ensure that the audit work was reasonable and viable.

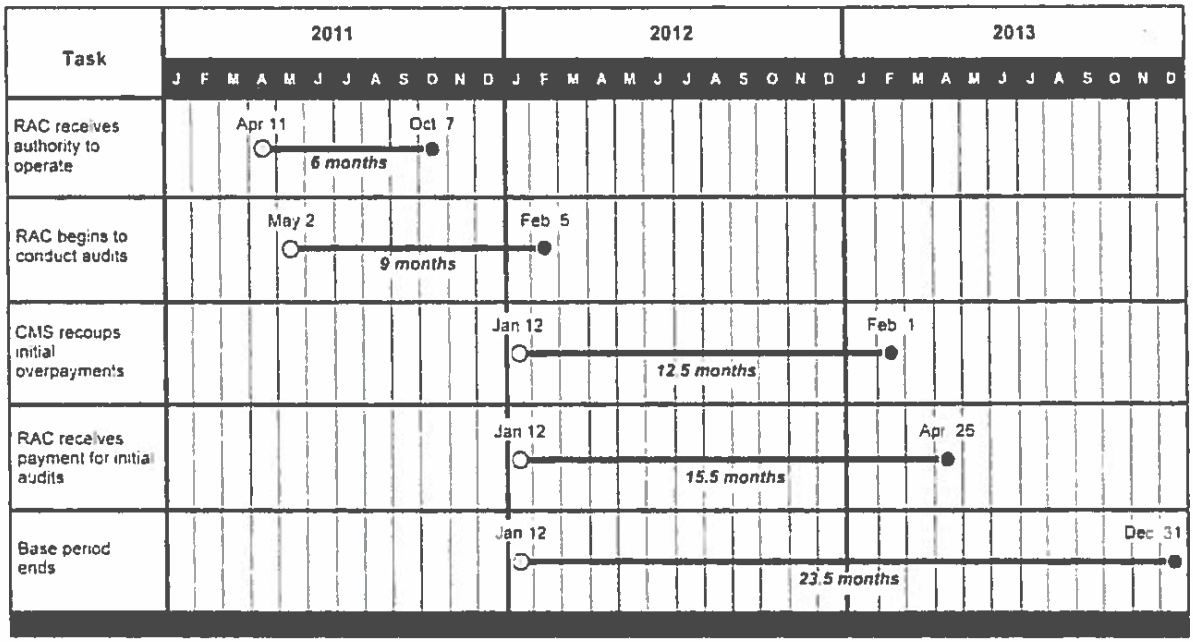
CMS officials said that once they recognized it was necessary to take a more prescriptive approach to directing the RAC's work, they began developing a statement of work for the RAC, which was intended to

[27]CMS also has used data validation in the recovery auditing activities in Medicare Parts A and B.

replace the performance work statement. This statement of work included the processes that the RAC should follow to obtain CMS approval for new audit topics and to conduct audits. CMS sent the Part D RAC the initial draft statement of work in December 2011, but it was not finalized until 2 years later in December 2013. CMS officials said that prior to finalizing the statement of work, CMS provided guidance to the RAC about its expectations for the work the RAC was to perform through contract modifications. However, a senior official with the RAC said that throughout this period, the RAC did not have a clear understanding about CMS's expectations regarding the work it should perform.

In addition to not setting clear expectations for the work the Part D RAC would perform, the agency also did not establish realistic timelines regarding the length of time required for CMS and the RAC to reach project milestones. The Part D RAC contract and implementation timeline, which CMS reviewed, did not adequately reflect the time needed to meet certain goals. (See fig. 2 for a comparison of the projected and actual timelines of key implementation activities.) For example, the RAC was required to ensure its information technology systems comply with the agency's information system security guidelines before CMS would grant it the authority to operate. The implementation timeline projected that the RAC would receive its authority to operate within 3 months of the contract award. However, the RAC did not receive its authority to operate until about 8 months after the contract was awarded. CMS officials told us that it typically takes up to a year for a new contractor to obtain its authority to operate.

Figure 2: Medicare Part D Recovery Audit Contractor (RAC) Program Implementation: Projected Versus Actual Timeline



○ When activity was projected to take place or to be completed

● When activity actually took place

Source: GAO analysis of CMS and RAC documents and interviews with CMS and RAC officials. | GAO-15-633

Furthermore, CMS did not begin collecting improper payments and the Part D RAC did not begin receiving contingency fees until more than a year after projected in the 2011 Part D RAC contract. The Part D RAC contract projected CMS would collect improper payments and the RAC receive contingency fees by January 2012, the end of the original base period of the contract. Instead, CMS began collecting improper payments more than 1 year later, in February 2013. The RAC did not begin receiving contingency fees until April 2013, 16 months later than projected. The RAC was required to cover its operating expenses until audits could begin, but a RAC official said that the RAC had not expected the projected implementation deadlines to be incorrect by more than a year. In response to concerns RAC officials raised about expenses the RAC incurred during perceived delays in receiving contingency fees,

CMS officials said they made several modifications to the Part D RAC contract. For example, CMS waived key personnel requirements and extended the base period of the contract eight times.

Since CMS faced challenges setting expectations about the work the Part D RAC would conduct and about the length of time required for CMS and the RAC to reach implementation milestones for the Part D RAC program, the RAC did not have a clear understanding about the work it should perform, and CMS did not recover improper payments for Part D until a year later than projected. Consistent with FAR requirements, agencies should clearly define requirements for services.[28] Furthermore, well-defined requirements are critical to ensuring the government gets what it needs from service contractors, as reported in our August 2011 review of opportunities to build strong foundations for better services contracts.[29] While requirements for a project can change at any point, officials must aggressively manage changes in requirements to avoid a negative effect on project results.[30]

CMS Has Not Completed Annual Evaluations of the Part D RAC but Has Conducted Other Oversight of the RAC's Performance

Since the Part D RAC contract was executed in January 2011, CMS has not completed any annual evaluations of the RAC's performance. CMS is currently in the process of finalizing an evaluation of the RAC's 2014 contract year performance. CMS has conducted other oversight of the RAC by establishing quality assurance procedures, such as progress meetings, inspection of deliverables, and audit finding review and acceptance.

[28]See 48 C.F.R. § 37.503(a).

[29]See GAO-11-672.

[30]See GAO-04-393.

CMS Has Not Completed Any Annual Evaluations of the RAC Since the RAC Contract Was Signed, but Evaluation for 2014 Is in Progress

CMS has not completed any annual evaluations of the Part D RAC's performance since the RAC contract was signed in January 2011. A senior official with the RAC said that despite the RAC's requesting annual evaluations, CMS had not conducted annual evaluations since the beginning of the contract and did not explain to the RAC why it did not conduct these evaluations. In March 2015, CMS officials acknowledged that they should have completed annual evaluations and said the agency has been behind in its evaluations of some of its contractors, including the RAC.[31] CMS officials said they started an evaluation of the RAC's contract year 2014 performance in December 2014. In May 2015, CMS officials finished the initial evaluation of the RAC's 2014 performance and provided the evaluation to the RAC for review and comment. The RAC has 60 days to submit a rebuttal to the agency's evaluation, prior to CMS completing the evaluation.[32] CMS officials said that the agency would not likely evaluate the RAC's performance prior to 2014, but did not indicate its plans for performance evaluation of the 2015 contract year.

In addition to not having completed an annual evaluation of the RAC, CMS has not established performance standards with measurable targets against which to evaluate the RAC's performance. A senior official with the RAC said that in addition to requesting evaluations, the RAC requested performance standards with targets but has not received them. CMS officials said that the January 2014 statement of work included performance standards for the RAC, such as deadlines for submitting deliverables and error rate targets for audit work—that is, the target percentage of incorrect determinations of potential improper payments the RAC should not exceed. However, CMS did not create a target for how often the RAC must meet deadlines for submitting deliverables. Also, CMS officials acknowledged that the error rate target was a threshold used to determine how much time the data validation contractor would be given to conduct its work. Therefore, it is not a direct performance standard with targets for the RAC. While performance standards with targets do not exist for the Part D RAC, they do exist for other Medicare RACs. For example, the Medicare Parts A and B RACs

[31]CMS officials reported that as of July 1, 2014, CMS had completed performance assessments for about 75 percent of contracts awarded

[32]If the RAC does not submit a rebuttal within 60 days, CMS will finalize the evaluation. If the RAC submits a rebuttal, CMS will consider this information and revise the evaluation if necessary prior to completing it

have targets of 100 percent compliance in both maintaining private health information security and responding to written correspondence within 30 calendar days of receipt.

Multiple federal standards and our prior work contain requirements and suggestions for conducting regular performance evaluations and developing performance measures, which would have provided CMS and the RAC with a basis for evaluating the RAC's performance.[33] In March 2013, the Office of Management and Budget issued a memorandum establishing targets in fiscal years 2013 through 2015 to improve compliance in conducting annual performance evaluations, with a target of 100 percent compliance in fiscal year 2015.[34] The FAR requires federal performance-based contracts to include measurable performance standards and a method for assessing contractor performance against performance standards, as well as to clearly define requirements for services.[35] According to federal internal control standards, federal agencies should conduct monitoring activities to assess the quality of performance over time and ensure that the findings of audits and other reviews are resolved promptly.[36] According to our prior work, performance measurement systems should include not only the collection of data on various metrics, but also a designation of specific performance measures, with realistically achievable performance targets against which to measure progress.[37] Since CMS had not completed annual contractor performance evaluations of the RAC using performance standards with measurable targets, CMS did not have a clear basis for assessing RAC performance in identifying improper payments and did not provide the RAC with targets against which the RAC could compare its performance.

[33]See GAO-11-646SP and GAO-13-278.

[34]See Office of Management and Budget, *Improving the Collection and Use of Information about Contractor Performance and Integrity* (Washington, D.C., March 6, 2013).

[35]48 C.F.R. §§ 37.601(b)(2), 37.503(a).

[36]See GAO/AIMD-00-21.3.1 and GAO-01-1008G.

[37]See GAO-13-278.

CMS Has Conducted Other Oversight of the RAC's Performance, Including Inspecting Its Work Products and Reviewing Its Audit Findings

While CMS has not conducted annual contractor performance evaluations, it has conducted other oversight by establishing quality assurance procedures through contract modifications, including a statement of work. CMS first established certain quality assurance procedures in April 2012, through a contract modification, to ensure compliance with the contract. The quality assurance procedures included progress meetings, inspection of deliverables, and audit finding review and acceptance. CMS revised its quality assurance procedures in the statement of work effective January 1, 2014. The new quality assurance procedures included

- monitoring RAC performance using measures including, but not limited to, demonstration of ongoing dialogue or meetings with the appropriate and necessary parties;
- requiring the RAC to "maintain the highest degree of quality" for all activities performed throughout the period of performance of the contract, and
- monitoring contractor performance using measures including, but not limited to, completeness and accuracy of data analysis and all deliverables.

However, these performance measures do not include targets, as called for in federal standards and our prior work.

CMS took steps to oversee the RAC's activities using these quality assurance procedures. For example, CMS officials said they conducted biweekly meetings with the RAC and held ad hoc meetings, as needed. CMS has also conducted oversight through audit finding review and acceptance. A data validation contractor reviews the RAC's findings, and with the RAC, it resolves any discrepancies that were found between the review results and the RAC's initial findings. CMS officials said that the data validation contractor reviews 100 percent of the RAC's findings, in part because of concerns CMS had about the quality of the RAC's initial audit work.

In addition to this ongoing oversight, in June 2014 CMS sent the RAC a letter titled "Areas of Concern for the RAC Part D Contract" to inform the RAC of concerns CMS program staff had about the overall performance of the contract. In the letter, CMS cited the quality assurance procedures in the statement of work as the source of its performance expectations for the RAC. CMS identified the following concerns about the RAC's audit work:

- Incorrect templates and materials being used by the RAC to communicate with plan sponsors;
- Quality issues with identifying potential improper payments and preparing documents for data validation during audit work; and
- Formatting errors and erroneous information in letters to be sent to plan sponsors.

While the RAC acknowledged that some of the concerns were valid, the RAC also disagreed with other concerns CMS raised. The RAC acknowledged that among other things, concerns CMS raised about some of the formatting errors and erroneous information were valid. However, the RAC rebutted some of CMS's concerns. For example, the RAC noted that there was no measurable target for evaluating the RAC's performance for one issue CMS raised. Specifically, CMS stated in the "Areas of Concern" letter that the agency had identified about 14,000 PDE records that the RAC had incorrectly determined to be potential improper payments, but did not state what would be an appropriate error rate. Since CMS did not set a maximum acceptable error rate, the RAC did not have an established target against which it could measure its work, and CMS did not have an established target with which to compare the RAC's performance. Without performance standards with targets, CMS is unable to adequately assess the quality of the RAC's performance in determining improper payments.

The RAC also noted in its response to CMS's Areas of Concern letter that CMS was assessing the RAC's performance on some of its audit work—identifying potential improper payments for excluded providers—using expectations that were not in place at the time the RAC was conducting the work. CMS stated in the second letter replying to the RAC's response that while it understood that the performance expectations referenced in the Areas of Concern letter were not directly in effect when the RAC was conducting the audit work, CMS's expectation was that all contractors would implement and maintain a standard of quality control at all times during their period of performance. When asked about the fact that performance expectations were established after the RAC's audit work was conducted, CMS officials told us that these concerns stemmed from expectations originally set in contract modifications and later formalized in the statement of work. However, our analysis of the contract modifications in place at the time of the RAC's work under question did not find contract language indicating how the RAC's performance would be evaluated, or measurable targets establishing a standard of quality control.

CMS Collected Less than $10 Million in Improper Payments as of May 2015, in Part Because of Challenges in Determining and Conducting Audit Activities

From January 2011 through May 2015, for five audit issues, CMS both authorized the RAC to conduct audit activities and pursued improper payment collections. Audit issues include two elements. (1) areas within the Part D program that should be considered for audits, and (2) the year or years for which PDE records are being audited.[38] The five audit issues CMS approved addressed three types of issues: (1) excluded providers, (2) unauthorized prescribers,[39] and (3) inappropriate refills of certain drugs regulated by the Drug Enforcement Administration under the Controlled Substances Act.[40]

CMS had collected less than $10 million in improper payments as of May 2015 for the five approved audit issues. CMS authorized the RAC to conduct audit activities that identified about $19.8 million in potential improper payments, and has collected about $9.7 million as of May 2015. Of the remaining approximately $10.1 million,

- $7.3 million in potential improper payments has been determined to be proper, for example, because the plan sponsor provided additional information verifying the amount of the Part D claim;
- $45,000 in potential improper payments has been identified as being uncollectible for various reasons, such as the plan sponsor's contract was terminated before audit activity took place;[41] and
- $2.8 million in improper payments remain that have not yet been collected, not yet determined to be proper, or not yet identified as being uncollectible. (See table 1 for each of the five approved audit issues for which CMS pursued collections, the amount CMS approved for the RAC to conduct audit activities, and the status of potential improper payments identified.)

[38]The areas within the Part D program that are considered for audits are those that have the potential to lead to improper payments and have measurable criteria for determining whether a particular payment is improper.

[39]Unauthorized prescribers are providers who do not have the authority to prescribe drugs for beneficiaries, such as veterinarians or dieticians, but have done so.

[40]This audit issue determines compliance with the Controlled Substances Act regarding the number of permitted refills for certain controlled substances outside of long-term care facilities.

[41]According to the 2014 statement of work, the RAC cannot review PDE records associated with plan sponsors with terminated contracts.

Table 1: Authorized Recovery Audit Contractor (RAC) Audit Activities and Associated Improper Payment Collections by Year Proposed, as of May 2015

Audit issue by year proposed	Affected year(s)	Amount of potential improper payments RAC identified for audit issues that the Centers for Medicare & Medicaid Services (CMS) has approved (thousands)	Amount collected (thousands)	Amount determined to be proper[a] (thousands)	Amount identified as being uncollectible[b] (thousands)	Amount not yet collected, not yet determined to be proper, or not yet identified as being uncollectible (thousands)
2012						
Excluded providers	2007	$8,376	$1,865	$6,511	$0	$0
2013						
Excluded providers	2008-2011	3,400	2,676	681	44	0
Unauthorized prescribers	2009-2011	4,559	4,513	45	2	0
Unauthorized prescribers	2012	716	649	66	0	0
Drug Enforcement Administration Controlled Substances Act refills (non-long-term care)	2010-2011	2,759	0	0	0	2,759
Total		**19,811**	**9,703**	**7,303**	**45**	**2,759**

Source: GAO analysis of CMS and RAC data. GAO-15-633

Note: The sum of the amounts for each audit issue may not equal the total because of rounding. The amount remaining to be collected, determined to be proper or identified as being uncollectible may not equal the amount for which CMS approved the RAC to conduct audit activities minus the sum of the amount collected, the amount determined to be proper, and the amount identified as being uncollectible because of rounding.

[a]These amounts were originally determined by the RAC to be potential improper payments but were subsequently determined to be proper for various reasons, such as the plan sponsor provided additional information verifying the amount of the Part D claim.

[b]These amounts were originally determined by the RAC to be potential improper payments but were subsequently identified as being uncollectible for various reasons, such as the plan sponsor's contract was terminated before audit activity took place. According to the 2014 statement of work, the RAC cannot review PDE records associated with plan sponsors with terminated contracts.

From the beginning of the contract in January 2011 until the statement of work became effective on January 1, 2014, CMS and the RAC faced challenges in determining audit issues on which to conduct work. As noted above, CMS did not initially authorize the RAC to begin conducting the audit work that the RAC had proposed and outlined in the performance work statement that became part of the contract. Instead, the first audit issue CMS approved the RAC to conduct was an audit of excluded providers for plan year 2007, which CMS suggested and which

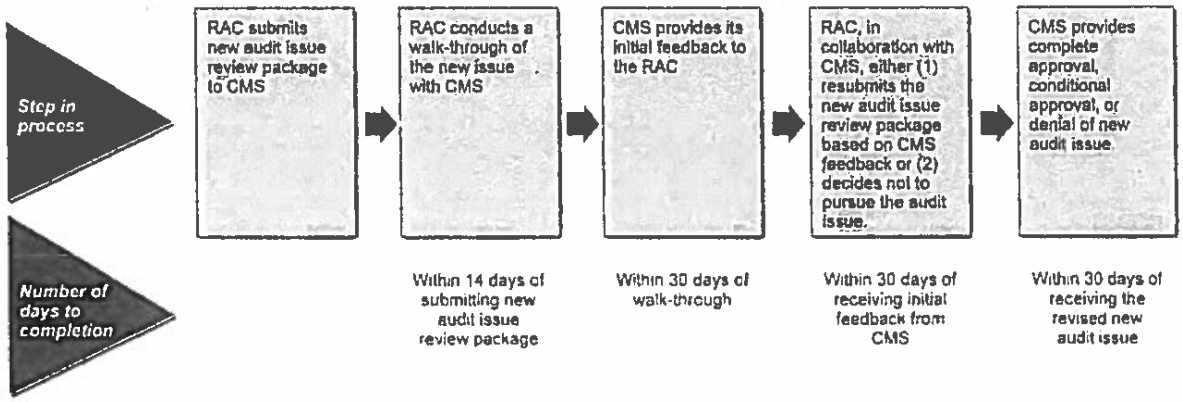
was included in a contract modification in February 2012. By the time the statement of work became effective on January 1, 2014, CMS had suggested that the RAC conduct audit work on three audit issues: excluded providers for plan year 2007, excluded providers for plan years 2008 through 2011, and unauthorized prescribers for plan years 2009 through 2011.[42] During that same time, CMS denied four of the six audit issues the RAC proposed. Of the remaining two audit issues, CMS later denied one issue and approved the other.[43] CMS denied issues for various reasons; for example, one audit issue was denied because the improper payments identified were outside the 4-year period prior to a plan sponsor's current plan year, which is the time limit for identifying improper payments.

After CMS and the RAC agreed to a new process for identifying, reviewing, and approving audit issues, which became effective on January 1, 2014, the RAC faced challenges in applying Part D regulations and CMS rules to develop audit methodologies. The statement of work CMS and the RAC agreed to included a new process by which the RAC would submit new audit issues for CMS's consideration. Figure 3 outlines the process the RAC and CMS follow to submit, evaluate, and decide on new audit issues. Under this process, CMS officials said, under some circumstances the RAC can resubmit an audit issue for a particular plan year once it has been denied. For example, CMS may deny the methodology the RAC used and ask the RAC to resubmit the audit issue using a different audit methodology.

[42]CMS also proposed the RAC conduct audit work on unauthorized prescribers for plan year 2012. This audit issue was proposed in November 2013, prior to the statement of work becoming effective, and approved in March 2014, when the statement of work was in effect.

[43]In March 2014, after the statement of work was in effect, CMS denied Drug Enforcement Administration Controlled Substances Act refills (non-long-term care) in plan year 2009 and approved Drug Enforcement Administration Controlled Substances Act refills (non-long-term care) in plan years 2010 through 2011.

Figure 3: Process the Recovery Audit Contractor (RAC) Has Used Since 2014 to Submit New Audit Issues for Centers for Medicare & Medicaid Services (CMS) Consideration



Source: GAO analysis of CMS document. | GAO-15-633

Since the new process took effect, the RAC has faced challenges in applying regulations and CMS rules to audit methodologies, resulting in CMS denials. For example,

- CMS denied the RAC's proposal to audit hospice care beneficiaries' PDE records because CMS guidance published in March 2014, 3 days after the RAC made the proposal, prevents CMS from performing hospice audits associated with Medicare Part D potential improper payments prior to May 1, 2014.[44] CMS noted in its denial that a retrospective audit would not be pursued at the time because previous CMS guidance was ambiguous and there were no objective criteria for plan sponsors to apply in determining whether the beneficiaries were eligible for Medicare Part D.
- CMS denied the RAC's proposal to audit deactivated prescribers in plan years 2010 through 2012 in part because the RAC's audit methodology included using a field in the PDE record that plan sponsors were not required to submit until January 1, 2013.

[44]The guidance was issued by the Centers for Medicare, a separate office within CMS from the Centers for Program Integrity, which oversees the Part D RAC.

CMS officials said they provide the RAC with assistance in developing audit issues; nevertheless, CMS has not approved any audit issues submitted since the new process took effect. CMS officials said they hold regular phone conversations between the RAC and program officials with subject matter expertise from several CMS program offices, and provide feedback to the RAC after an audit issue is submitted. However, since the new process took effect in January 2014, the RAC has proposed nine audit issues, and CMS has not approved any of them. (See table 2 for each of the nine denied audit issues.)

Table 2: Audit Issues the Centers for Medicare & Medicaid Services (CMS) Denied under Audit Process Effective January 2014, as of May 2015

Audit issue	Affected year(s)	Date Recovery Audit Contractor (RAC) submitted audit issue for CMS review	Date CMS issued denial
Excluded pharmacists	2009-2011	January 2, 2014	February 19, 2014
Deactivated prescribers	2009	February 4, 2014	March 18, 2014
Incarcerated beneficiaries	2009	March 7, 2014	March 18, 2014
Hospice care	2009-2011	March 7, 2014	April 18, 2014
Drug Enforcement Administration Controlled Substances Act refills (long-term care)	2009-2011	February 4, 2014	April 21, 2014
Deactivated prescribers	2010-2012	February 4, 2014	May 19, 2014
Incarcerated beneficiaries	2010-2012	March 7, 2014	May 21, 2014
Expired prescriptions	2010-2011	August 25, 2014	February 17, 2015
Duplicate payments	2010-2012	January 2, 2014	April 24, 2015

Source: GAO analysis of CMS and RAC data. | GAO-15-833

Challenges faced by CMS and the RAC have resulted in few audit issues being approved and therefore a small amount of improper payments being identified and collected relative to CMS's estimates of improper payments in Medicare Part D. In more than 4 years, initial CMS and RAC challenges in determining the audit work to conduct and later RAC challenges in determining how to apply regulations and rules to audit issues have resulted in CMS's approving 1 of the 15 audit issues the RAC proposed, and no approvals for issues submitted since the new audit issue process took effect. The RAC can only resubmit an audit issue under some circumstances, once it has been denied, so a denial not only results in lost time and effort, but also may result in a lost opportunity to identify and collect potential improper payments. In addition, the RAC may only identify potential improper payments on PDE records within

4 years of the plan sponsor's current plan year.[45] Therefore, as each year passes, another prior plan year can no longer be audited by the RAC.

Both CMS and the RAC are charged with reducing Medicare Part D improper payments. CMS has a goal to reduce improper payments in Medicare Part D, according to the fiscal year 2016 Annual Performance Plan and Report.[46] The RAC's mission is to reduce Medicare improper payments through the efficient detection and collection of improper payments, using a methodology that maximizes recoveries as well as meets all regulatory requirements, according to CMS's statement of objectives for the RAC. In addition, federal internal control standards state that agencies should have effective and efficient processes in place that enforce management's directives and that these processes are monitored. The $9.7 million in improper payments that CMS has collected since 2011 is a relatively small amount compared to CMS's estimated improper payments in Medicare Part D of $1.9 billion in 2014 alone. If the process for identifying, reviewing, and approving new audit issues was more efficient in developing appropriate issues, the process would likely have resulted in more issues being approved each year of the RAC contract and more improper payments being identified and collected.

Conclusions

Given Medicare's vulnerability to improper payments, it is important to develop a RAC program that effectively identifies and recovers those improper payments. The effectiveness of the RAC program, which began in January 2011, has been hindered by various challenges faced by both CMS and the RAC that resulted in relatively little in improper payment collections. The first RAC contract is ending on December 31, 2015, and CMS is contemplating how to solicit contractors for the next RAC contract. Among CMS's considerations is obtaining RAC services on the open market using a full and open competitive solicitation. As CMS considers its upcoming solicitation for the next contract period, it has an opportunity to address the challenges it and the RAC faced during the first contract. Establishing clear work statements, realistic timelines, and an improved process for identifying, reviewing, and approving audit issues would provide more assurance that audit work can be conducted

[45]See 42 C F R § 423 346

[46]See Department of Health and Human Services, *Fiscal Year 2016 Annual Performance Plan and Report* (Washington, D C , February 2015)

more effectively and efficiently through the next RAC contract. Additionally, conducting annual performance evaluations against measurable targets would allow CMS to regularly assess the effectiveness of a RAC contractor and identify and address any areas for improvement. Setting in place these improvements would significantly increase the likelihood of identifying and collecting more improper payments in the Part D program.

Recommendations for Executive Action

As CMS prepares to solicit the next RAC contract(s), we recommend that the Administrator of CMS take the following three actions to improve the agency's RAC program operations and contractor oversight:

- Ensure that work statements included in solicitations for contract proposals and the executed contract(s) set clear expectations about the work CMS intends the RAC to perform and that time frames are established that reflect the time needed to reach milestones.
- Conduct annual evaluations of the RAC's performance against measurable performance standards to provide a clear basis on which CMS and the RAC can assess RAC performance in identifying improper payments.
- Review the agency's process for identifying, reviewing, and approving new audit issues to identify process improvements that will help ensure the efficient development of appropriate audit issues (i.e., reduce audit issue denials and increase audit issue approvals) and thereby maximize the collection of improper payments.

Agency Comments

We provided a draft of this report to HHS for comment, and its comments are reprinted in appendix I. HHS also provided technical comments, which we incorporated as appropriate. We shared portions of the draft report with the current Part D RAC, the contractor provided oral technical comments, which we incorporated as appropriate.

In commenting on this report, HHS agreed with our three recommendations. HHS stated that it plans to select a contractor to serve as the Part D RAC under new contract terms in January 2016. For this Part D RAC, HHS stated that it will address our recommendations by setting clear expectations, reasonable timelines, and measurable performance standards, as well as developing improved processes for reviewing new audit topics by strengthening the collaboration between CMS's policy experts, PDE review experts, and data analytics experts, as well as the Part D RAC's team of analysts. In its comments, HHS also

noted additional steps it has taken to strengthen Part D program integrity, such as enrolling prescribers of Part D drugs in Medicare by January 2016, and subjecting these prescribers to the screening procedures used for other Medicare providers. HHS also created a web-based tool to allow CMS, law enforcement, and plan sponsors to share information and coordinate actions against high-risk pharmacies.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, the Administrator of the Centers for Medicare & Medicaid Services, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

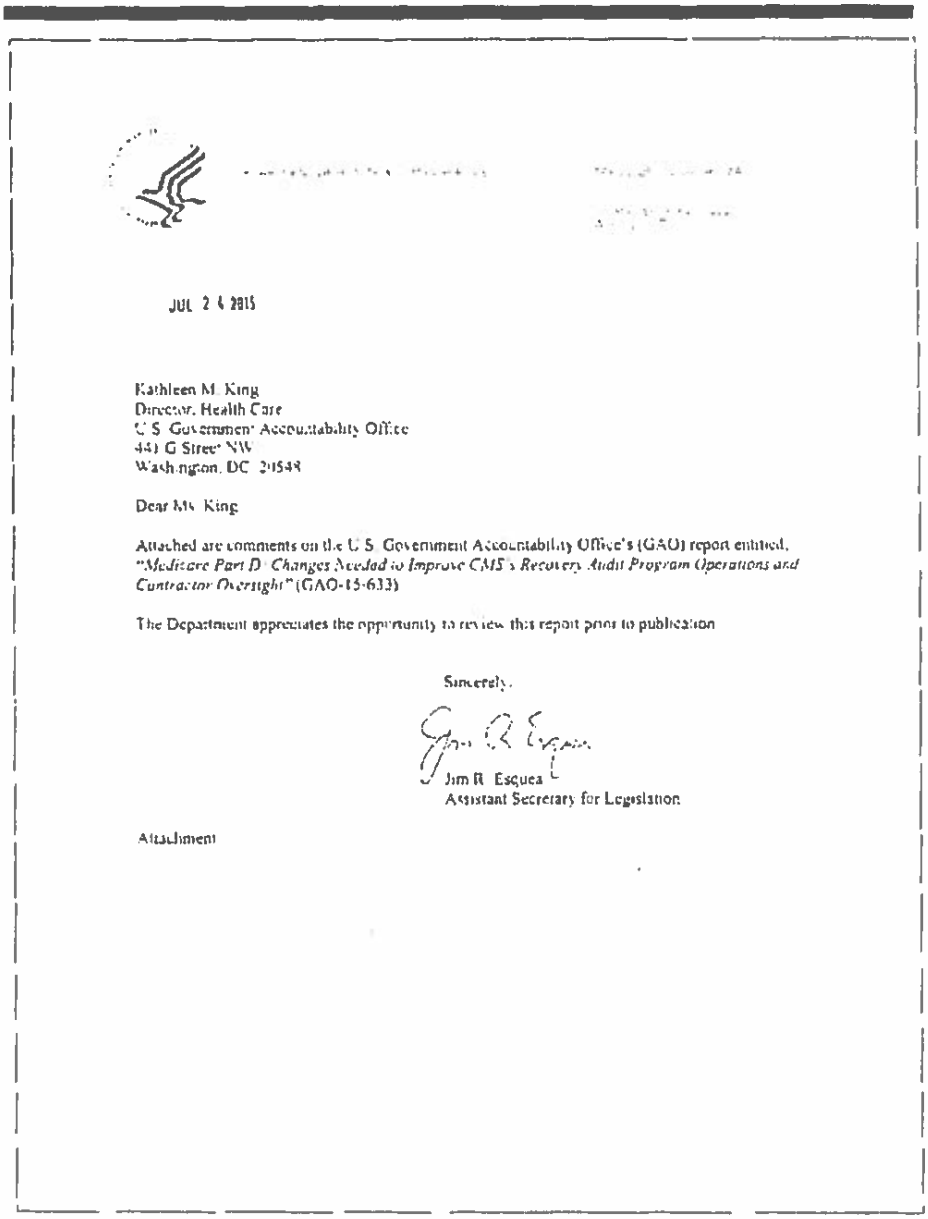
If you or your staff have any questions about this report, please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix II.

Sincerely yours,

Kathleen M. King

Kathleen M. King
Director, Health Care

Appendix I: Comments from the Department of Health and Human Services



JUL 24 2015

Kathleen M. King
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. King:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"Medicare Part D: Changes Needed to Improve CMS's Recovery Audit Program Operations and Contractor Oversight"* (GAO-15-633).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

33

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: MEDICARE PART D: CHANGES NEEDED TO IMPROVE CMS'S RECOVERY AUDIT PROGRAM OPERATIONS AND CONTRACTOR OVERSIGHT (GAO-15-633)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. HHS is strongly committed to program integrity in the Part D program and takes seriously our responsibility to protect taxpayer dollars by recovering improper payments.

The Part D Recovery Audit Contractor (RAC) is one element of CMS' Medicare Part D program integrity strategy. The Part D RAC identifies and corrects improper payments to Part D plan sponsors, provides information to CMS to help prevent future improper payments, and refers any potential fraud findings identified during the auditing process for further review.

In addition to the Part D RAC, HHS has a number of ongoing initiatives to strengthen Part D program integrity. HHS is actively working to enroll over 400,000 prescribers of Part D drugs into Medicare by January 2016. These prescribers will be subject to the risk-based screening procedures of other Medicare providers—including unannounced site visits, criminal background checks, and fingerprinting—that have resulted in the removal of nearly 575,000 provider and supplier enrollments from the Medicare program since the enactment of the Affordable Care Act. Beginning in June 2016, HHS will require Part D plans to stop filling and paying for prescriptions from unenrolled providers. However, in order to minimize the potential for disrupting beneficiaries' access to needed Part D medications and compromising continuity of care, Part D sponsors will be required to cover a three month provisional supply of the drug and provide beneficiaries with individualized written notice before denying a Part D claim or beneficiary request for reimbursement on the basis of a prescriber being neither enrolled in an approved status nor validly opted out of Medicare. The three month provisional supply is intended to give the prescriber time to enroll in Medicare or opt-out. Requiring such prescribers to enroll in Medicare will help HHS make sure that Part D drugs are only prescribed by qualified individuals.

HHS is taking additional proactive steps to safeguard the program integrity of the Part D benefit. HHS has a program in place to identify vulnerabilities and perform analyses to target and recover improper payments in Part D. In fiscal years 2013, 2014, and 2015, this program led to the recovery of $78.5 million. HHS regularly monitors pharmacy billing patterns and collaborates with Part D sponsors to perform audits or take other appropriate actions on high-risk pharmacies. HHS also works with plan sponsors to prevent overutilization of certain prescribed medications and share information about beneficiaries that may over-utilize prescription drugs. In April 2015, HHS launched a web-based tool to allow CMS, law enforcement, and plan sponsors to share information and coordinate actions against high-risk pharmacies.

HHS established quality assurance procedures to provide appropriate oversight and assistance to the Part D RAC throughout the duration of the contract. In order to facilitate coordination on audit issues and quality assurance procedures, HHS schedules bi-weekly meetings with the Part D RAC. HHS collaborated with the Part D RAC to find appropriate audit issues it could examine and to modify the contract accordingly. HHS also partnered with a Data Validation Contractor to verify the Part D RAC's findings. In addition, HHS provided significant assistance in

developing or revising audit methodologies to properly identify improper payments and minimize false positives in the Part D RAC's audits

HHS appreciates GAO's efforts on this issue and will work to strengthen the Part D RAC program moving forward. HHS plans to select a contractor to begin serving as the Part D RAC under new contract terms in January 2016. The new contractor will be chosen through a full and open competition which will allow a wider range of entities to compete than if the contract were offered through the Federal Supply Schedule. HHS will set clear expectations, reasonable timelines, and measurable performance standards for the new Part D RAC. We will also develop improved processes for reviewing new audit topics to maximize the collection of improper payments.

GAO's recommendations and HHS' responses are below.

GAO Recommendation
Ensure that work statements included in solicitations for contract proposals and the executed contract(s) set clear expectations about the work CMS intends the RAC to perform and that time frames are established that reflect the time needed to reach milestones.

HHS Response
HHS concurs with GAO's recommendation. Through the contracting process, HHS is establishing clear expectations about the work the new Part D RAC is expected to perform. In addition, HHS will establish reasonable time frames for the contractor to reach milestones.

GAO Recommendation
Conduct annual evaluations of the RAC's performance against measurable performance standards to provide a clear basis on which CMS and the RAC can assess RAC performance in identifying improper payments.

HHS Response
HHS concurs with GAO's recommendation. HHS will develop measurable performance standards for the new Part D RAC to meet and conduct annual evaluations of the new Part D RAC against these standards.

GAO Recommendation
Review the agency's processes for reviewing, identifying, and approving new audit issues to identify process improvements that will help ensure the efficient development of appropriate audit issues (i.e., reduce audit issue denials and increase audit issue approvals) and thereby maximize the collection of improper payments.

HHS Response
HHS concurs with GAO's recommendation. HHS will work to identify and implement process improvements that will help identify appropriate audit topics and develop a sound methodology to maximize the collection of improper payments. CMS will improve the process for reviewing, identifying, and approving new audit topics that leverages the best practices for developing sophisticated analytics to support the Fraud Prevention System (FPS). For example, the FPS analytics team has strong collaborative engagement between a team of policy experts, data analytics experts, and review experts with our program integrity contractors. That process can be mirrored for the Part D RAC through strengthening the collaboration between CMS policy experts, PDE review experts, and data analytics experts and the team of analysts from the Part D

RAC. Additionally, CMS is developing ways to leverage data from the Part D program to strengthen FPS models that identify Medicare FFS providers with behaviors that require intervention. Since the FPS combines information by FFS provider, the information from Part D will not change the focus on the provider, but will be used to develop new risk factors. For example, CMS will include in the FPS a model that monitors for high-risk prescribers as one of the criteria for elevated risk. By incorporating the analysis of high-risk prescribers into the FPS, CMS will be better able to investigate and take swift action on bad actors in a coordinated way. Through early and ongoing engagement, audit topics can be discussed and improved to make sure that the Part D RAC and CMS partner to the maximum recovery of improper payments.

HHS thanks GAO for their efforts in this area and looks forward to working with GAO on this and other areas in the future.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact	Kathleen M. King, (202) 512-7114 or kingk@gao.gov.
Staff Acknowledgments	In addition to the contact named above, Karen Doran (Assistant Director), Muriel Brown, Christine Davis, Peter Mangano, Roseanne Price, Mandy Pusey, and Jennifer Whitworth made key contributions to this report.

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Congressional Relations	Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548
Public Affairs	Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548

Please Print on Recycled Paper

December 17, 2013 CMS Email

EXHIBIT 16

From: Schultz, Theresa A. (CMS/OAGM)
Sent: Tuesday, December 17, 2013 10:14 PM
To: Downs, Tanette N. (CMS/CPI); Majestic, Mark (CMS/CPI); Brown, Sonja J. (CMS/CPI); Thomas, India M. (CMS/CPI)
Cc: Collins, Pamela K. (CMS/OAGM); Hoey, Nicole E. (CMS/OAGM); Menefee, Justin (CMS/OAGM); Schultz, Theresa A. (CMS/OAGM)
Subject: FW: RAC D

Importance: High

Another matter of negotiation for the Part D RAC contract was regarding the period of performance. ACLR believed that it should be entitled to an extension of the option periods equal to the extension of the base period. In other words, we extended the base period for 2 years.

The original contract was awarded as a one year base and four optional periods. Since there were so many issues with the PWS and since the revised SOW was not yet finalized, we extended the Base several times, which amounted to a total base period of 3 years. The modifications were silent on the option periods.

	As Awarded	Actual
Base	1/13/11 - 1/12/12	1/13/11 - 12/31/13
OY1	1/13/12 - 1/12/13	not stated
OY2	1/12/13 - 1/12/14	not stated
OY3	1/12/14 - 1/12/15	not stated
OY4	1/12/15 - 1/12/16	not stated

Now that we are close to finalizing the SOW and exercising the first option period, ACLR has told us that they were under the impression that they would still get 4 optional periods. In other words, they were of the understanding that the contract would be extended for two additional option years, such as:

	As Awarded	ACLR Understanding
Base	1/13/11 - 1/12/12	1/13/11 - 12/31/13
OY1	1/13/12 - 1/12/13	1/1/14 – 12/31/14
OY2	1/12/13 - 1/12/14	1/1/15 – 12/31/15
OY3	1/12/14 - 1/12/15	1/1/16 – 12/31/16
OY4	1/12/15 - 1/12/16	1/1/17 – 12/31/17

We were not of the same understanding as ACLR. After several conversations with them about the option periods, we consulted OGC. ACLR had cited the "government delay of work" clause as the justification for extending the period. [redacted] Our concern has always been that this contract was awarded with the acceptance of the PWS, but the reality is that we never authorized the contractor to perform IAW the PWS. [redacted]

We believe, at a minimum, we should have two additional options and then another year for administrative and payment purposes. Below are two potential options for us moving forward. I am comfortable with either one. We may find it easier to get them to agree to the 16% if we offer Option B. Please let us know your thoughts. We have a meeting with ACLR tomorrow morning at 10:30, so if we could get your input before then, that would be great. Thanks for your time.

OPTION A

PERIOD OF PERFORMANCE

The base period of the task order is from January 13, 2011 through December 31, 2013. The task order also includes two (2) 12-month options, plus a 12 ½ month option for purposes of appeals and payment.

Base Period	January 13, 2011 through December 31, 2013
Option Period 1	January 1, 2014 through December 31, 2014
Option Period 1 – Administrative and Appeals Option	January 1, 2015 through January 24, 2016
Option Period 2	January 1, 2015 through December 31, 2015
Option Period 2 - Administrative and Appeals Option	January 1, 2016 through January 24, 2017

Only one Administrative and Appeals Option will be exercised. The Administrative and Appeals option is for the purpose of the RAC to continue to work through the appeals process and for the RAC to receive payment of audit issues approved/processed during the option period. If Option Period 2 is NOT exercised, The Option Period 1-Administrative and Appeals Option will be exercised for the purpose of the RAC to work thru the appeals process and obtain its contingency fee on amounts recovered. If Option Period 2 is exercised, Option Period 2-Administrative and Appeals Option will be exercised.

The last date for the RAC to submit a New Audit Issue Review Package for each Option period is September 18th. This will allow the 104 day approval process to take place prior to the end of the option period.

OPTION B

PERIOD OF PERFORMANCE

The base period of the task order is from January 13, 2011 through December 31, 2013. The task order also includes four (4) 12-month options, plus a 12 ½ month option at the end of the contract for purposes of appeals and payment.

Description	Period of Performance
Base Period	January 13, 2011 through December 31, 2013
Option Period 1	January 1, 2014 through December 31, 2014
Option Period 2	January 1, 2015 through December 31, 2015
Option Period 3	January 1, 2016 through December 31, 2016
Option Period 4	January 1, 2017 through December 31, 2017
Administrative and Appeals Option*	January 1, 2018 through January 24, 2019

*At the end the contract, an Administrative and Appeals Option will be exercised. Only one Administrative and Appeals Option will be exercised. The Administrative and Appeals option is for the purpose of the RAC to continue to work through the appeals process and for the RAC to receive payment of audit issues approved/processed during the option period.
For example, If Option Period 1 is exercised but Option Period 2 is not, the Administrative and Appeals option will be exercised for the period of 12 ½ months following the end of the option period (January 1, 2015 through January 24, 2016). If all four options are exercised, the Administrative and Appeals option will be exercised for the period of January 1, 2018 through January 24, 2019.

The last date for the RAC to submit a New Audit Issue Review Package for each Option period is September 18th. This will allow the 104 day approval process to take place prior to the end of the option period.

From: Simpson, Christine (HHS/OGC)
Sent: Tuesday, December 17, 2013 11:18 AM
To: Schultz, Theresa A. (CMS/OAGM)
Cc: Hoey, Nicole E. (CMS/OAGM); Pierre, Jeffri (HHS/OGC)
Subject: FW: RAC D
Importance: High

Theresa,

[redacted]

Crissy Simpson

HHS/OS/OGC
(410)786-1384

December 2014 Emails

EXHIBIT 17

From: Thomas, India M. (CMS/CPI)
Sent: Tuesday, December 09, 2014 9:49 PM
To: Schultz, Theresa A. (CMS/OAGM)
Cc: Hebbel, Brian W. (CMS/OAGM); Hoey, Nicole E. (CMS/OAGM); Burns, Morgan L. (CMS/CPI); Brown, Sonja J. (CMS/CPI); Abankwah, Rosalind M. (CMS/CPI)
Subject: FW: ACLR Letter
Attachments: ACLR Response Final V1 mblis(SA) (3)lis.docx

Theresa,

CPI senior management cleared the attached letter. Please move forward with sending it through the signature process. Let us know if you need anything else.

Thanks,

India M. Thomas
Health Insurance Specialist
CMS/CPI/IAG/DPOA
ext 61152

From: Schultz, Theresa A. (CMS/OAGM)
Sent: Monday, December 08, 2014 10:43 AM
To: Abankwah, Rosalind M. (CMS/CPI)
Cc: Thomas, India M. (CMS/CPI); Brown, Sonja J. (CMS/CPI); Burns, Morgan L. (CMS/CPI); Hoey, Nicole E. (CMS/OAGM); Hebbel, Brian W. (CMS/OAGM)
Subject: RE: ACLR Letter

Rosalind,

We reviewed CPI comments and do not think there is anything for us to respond to. It appears as though the only open question has to do with who's responsibility was it to approve the PWS. The technical evaluation panel would have approved the PWS prior to award. As we have stated in the past, this is where CMS is very vulnerable. If the PWS did not take into consideration CMS Policies and processes, it should not have been accepted in the first place.

Nicole and I are ok with the changes in the letter. As a result, are you ok with us sending this revised letter through the signature process?

Thanks
theresa

From: Abankwah, Rosalind M. (CMS/CPI)
Sent: Friday, December 05, 2014 8:18 PM
To: Schultz, Theresa A. (CMS/OAGM)
Cc: Thomas, India M. (CMS/CPI); Brown, Sonja J. (CMS/CPI); Burns, Morgan L. (CMS/CPI)
Subject: RE: ACLR Letter

Theresa,

We forwarded your ACLR draft letter to CPI leadership for review and comment. There are some questions that we were not able to answer. We have provided a response to the extent possible.

Please review and respond to our leadership comments/questions. Please copy all as I will be out of the office most of next week.

Thank you,
Rosalind

From: Burns, Morgan L. (CMS/CPI)
Sent: Friday, December 05, 2014 9:S8 AM
To: Abankwah, Rosalind M. (CMS/CPI)
Cc: Downs, Tanette N. (CMS/CPI); Majestic, Mark (CMS/CPI); Campbell, Joi L. (CMS/CPI); Hughes, Paul J. (CMS/CPI)
Subject: RE: ACLR Letter

Hi Rosalind – please see comments and edits from Shantanu, Lis and me. let me know if you have any questions, thanks!

From: Abankwah, Rosalind M. (CMS/CPI)
Sent: Thursday, December 04, 2014 2:16 PM
To: Burns, Morgan L. (CMS/CPI)
Cc: Downs, Tanette N. (CMS/CPI); Majestic, Mark (CMS/CPI); Campbell, Joi L. (CMS/CPI); Hughes, Paul J. (CMS/CPI)
Subject: FW: ACLR Letter

Morgan,
We have responded to the attached incoming correspondence from ACLR. We think the response should be a joint signature from Shantanu and Dan Kane.

Please forward to Shantanu for review.

Thanks,
Rosalind

From: Schultz, Theresa A. (CMS/OAGM)
Sent: Thursday, December 04, 2014 1:22 PM
To: Waskiewicz, Beth (CMS/OAGM); Hebbel, Brian W. (CMS/OAGM)
Cc: Hoey, Nicole E. (CMS/OAGM); Menefee, Justin (CMS/OAGM); Downs, Tanette N. (CMS/CPI); Abankwah, Rosalind M. (CMS/CPI); Brown, Sonja J. (CMS/CPI); Thomas, India M. (CMS/CPI); Brown, Camille J. (CMS/CCIIO)
Subject: ACLR Letter

Beth/Brian,
Attached is OAGM/CPI consolidated proposed response to ACLR's letter to President Obama. I recommended that this letter be jointly signed by Dan and Shantanu Agrawal, if possible. Please review and let me know if you have any recommended changes. This is a SWIFT action with a due date of Monday 12/8/14.
Thank you
Theresa Schultz

From: Kim, Jung S. (CMS/CPI)
Sent: Tuesday, November 18, 2014 03:57 PM

To: Gillespie, Craig (CMS/CPI); UnterBrink, Raymond K. (CMS/CPI)
Cc: Downs, Tanette N. (CMS/CPI)
Subject: FYI

Good Afternoon – The attached incoming is informational for CPI. Review and distribute as necessary.

Jung S. Kim
Program Analyst
Center for Program Integrity
Business Services Group
Centers for Medicare & Medicaid Services
7500 Security Blvd. AR-05-00
Baltimore, MD 21244

Excerpts of Part III to OMB Circular A-123, Appendix C

EXHIBIT 18

A06747

THE DIRECTOR

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D C 20503

March 22, 2010

M-10-13

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Peter R. Orszag
Director

SUBJECT: Issuance of Part III to OMB Circular A-123, Appendix C

Annually, taxpayers lose billions of dollars in wasteful improper payments by the Federal government to individuals, organizations, and contractors. These errors and mistakes are unacceptable and continue to erode public trust at a time when taxpayers are demanding that their dollars be spent wisely and effectively. Effective spending includes protecting access to Federal programs for their intended beneficiaries, especially the most vulnerable.

Despite efforts to reduce improper payments, agencies reported nearly $100 billion in improper payments for Fiscal Year 2009. In response to this unprecedented level of improper payments, on November 20, 2009, the President signed Executive Order 13520, Reducing Improper Payments. The Executive Order will reduce improper payments by boosting transparency, holding agencies accountable for reducing improper payments, and examining creating incentives for states and other entities to reduce improper payments and increasing penalties for contractors who fail to timely disclose improper payments.

OMB is now issuing the attached government-wide guidance on the implementation of the Executive Order. This guidance is contained in a new Part III to Appendix C of OMB Circular A-123[1]. Significant components of OMB's guidance include:

- Specifying responsibilities for agency accountable officials;
- Determining the programs subject to the Executive Order (i.e., high priority-programs);
- Defining supplemental measures and targets for high-priority programs;
- Establishing reporting requirements under the Executive Order; and
- Establishing procedures to identify entities with outstanding improper payments.

[1] In August 2006, OMB issued Parts I and II to Appendix C of OMB Circular A-123. Parts I and II are implementing guidance for the Improper Payments Information Act of 2002 (IPIA) (Pub. L. No. 107-300), and section 831 of the Defense Authorization Act for Fiscal Year 2002 (Pub. L. No. 107-107, codified at 31 U.S.C. §§ 3561-3567), also known as the Recovery Auditing Act.

This updated guidance is effective for agencies to use immediately and for Fiscal Year 2010 reporting. Please contact Joseph Pika in OMB's Office of Federal Financial Management (202-395-1040) with any questions regarding this guidance.

Attachment

APPENDIX C

Requirements for
Effective Measurement and Remediation
of Improper Payments

TABLE OF CONTENTS

Part I. Improper Payments Information Act Reporting

This Guidance implements the requirements of the Improper Payments Information Act of 2002 (IPIA) (Pub. L. No. 107-300). OMB Memorandum M-03-13, "Improper Payments Information Act of 2002 (Public Law No: 107-300)." issued May 21, 2003, is hereby modified and incorporated as Appendix C, Part I. to OMB Circular A-123, *Management's Responsibility for Internal Controls*.

A. What is an erroneous or improper payment? (The term "erroneous payment" and "improper payment" have the same meaning in this Guidance)

An improper payment is any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative, or other legally applicable requirements. Incorrect amounts are overpayments and underpayments (including inappropriate denials of payment or service). An improper payment includes any payment that was made to an ineligible recipient or for an ineligible service, duplicate payments, payments for services not received, and payments that are for the incorrect amount. In addition, when an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment must also be considered an error.[1]

The term "payment" in this Guidance means any payment (including a commitment for future payment, such as a loan guarantee) that is

- derived from Federal funds or other Federal sources;
- ultimately reimbursed from Federal funds or resources; or
- made by a Federal agency, a Federal contractor, a governmental or other organization administering a Federal program or activity.

This includes Federal awards subject to the Single Audit Act Amendments of 1996 (SAA) (Pub. L. No. 104-156) that are expended by both recipients and sub-recipients. In limited cases, and with prior approval from OMB, an agency may implement a measurement approach that excludes improper payments that have been subsequently corrected and recovered from the annual total reported in its Performance and Accountability Report (PAR).

B. What agencies are required to comply with the requirements of the Improper Payments Information Act of 2002 (IPIA) (Pub. L. No. 107-300)?

The agencies required to comply with IPIA are defined broadly as "a[ny] department, agency, or instrumentality in the executive branch of the United States" as defined in title 31, section 102 of the United States Code.

[1] Agencies that use a different method for reporting errors that result from documentation issues must present their proposal to OMB for review. Any deviation from the methodology described above must be approved in advance by OMB.

C. What is a program or activity? (The term "program and activity" is referred to in this Guidance as "program.")

The Act anticipates that agencies will examine the risk of erroneous payments in all programs and activities they administer, beyond those listed in the former Section 57 of OMB Circular A-11. The term program includes activities or sets of activities recognized as programs by the public, OMB, or Congress, as well as those that entail program management or policy direction. This definition includes, but is not limited to, all grants including competitive grant programs and block/formula grant programs, regulatory activities, research and development activities, direct Federal programs, procurements including capital assets and service acquisition, and credit programs. It also includes the activities engaged in by the agency in support of its programs.

For Federal awards subject to the SAA or otherwise listed in the Catalog of Federal Domestic Assistance (CFDA), Federal agencies should consider using the groupings in the OMB Circular A-133 Compliance Supplement and the CFDA. However, unless otherwise specified in OMB Circular A-11, each Federal agency, after consultation with OMB, is authorized to determine the grouping of programs which most clearly identifies and reports erroneous payments for their agency. Agencies must not put programs into groupings that result in significant error rates being masked by the large size or scope of such a grouping. For transparency, the basis for these groupings must be reported in the agency's annual PAR.

D. What constitutes an improper loan or loan guarantee payment?

Direct loans:
Under a direct loan program, improper payments may include disbursements to borrowers or other third-party payments that are based on incomplete, inaccurate, or fraudulent information. They may also include duplicate disbursements, disbursements in the incorrect amount, or loan funds used for purposes other than those allowed by law, program regulations, or agency policy.

Loan guarantee:
Under a loan guarantee program, an improper payment may include disbursements to intermediaries, third-parties for defaults, delinquencies, interest and other subsidies, or other payments that are based on incomplete, inaccurate, or fraudulent information. They may also include duplicate disbursements, disbursements in the incorrect amount, or any disbursements that are not in compliance with law, program regulations, or agency policy.

E. What are agencies required to do?

Agencies are required to review all programs and activities they administer and identify those which may be susceptible to significant erroneous payments. This includes payments from Federal awards subject to the SAA made by recipients and sub-recipients. Annual risk assessments are required for all agency programs where the level of risk is unknown until the risk level is determined and the baseline estimates are established (if applicable). For agency programs deemed not risk susceptible risk assessments are required every three years. Agencies need not conduct formal risk assessments for those programs in which improper payment baselines are already established, are in the process of being measured, or will be measured by an

CMS Part D RAC Overview

EXHIBIT 19

A02201

CMS Center For Program Integrity (CPI) Part D Recovery Audit Contractor (RAC) Program Overview

Frank Chartier
Division of Plan Oversight & Accountability

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DP1128

A02202

RAC Overview Agenda Topics

- RAC Program History and Background
- Part D RAC Audit Process
  - Pre-Audit Phase
  - Audit Phase
  - Post-Audit Phase
- Wrap Up

History and Background of the Recovery Audit Contractor (RAC) Program

A02203

- The RAC program was congressionally-mandated to identify improper payments and recoup overpayments
- The RAC program is responsible for:
  - Identifying and correcting past improper payments to Medicare providers and Sponsoring Organizations (SOs)
  - Implementing procedures to help CMS, SOs, Medicare carriers, Fiscal Intermediaries, and Medicare Administrative Contractors (MACs) implement actions to prevent future improper payments
- CMS' Center for Program Integrity (CPI) currently oversees the Part D RAC program

A02204

History of Part D and the Medicare RAC Program

- Part D, the Medicare Prescription Drug Benefit, was enacted via Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173) in December 2003
- The FFS RAC program was implemented as a demonstration project through The Tax Relief and Health Care Act of 2006
- CMS permanently implemented the FFS RAC program on a nationwide basis in October 2009
- Signed in 2010, Section 6411(b) of the Affordable Care Act (ACA) expanded the use of RACs to Medicare Parts C and D

DP1131

A02205

The Part D RAC Program

The Part D RAC:

- Analyzes previously paid individual Medicare Part D claims/ Prescription Drug Events (PDEs) and other financial information
- Corrects past improper payments to Medicare Part D SOs
- Provides information to CMS to help prevent future improper payments
- Refers any potential fraud findings identified during the auditing process to the MEDIC, CMS's contracted field agent that assists with detection and prevention of fraud, waste and abuse in the Parts C and D programs

A02206

RAC Overview Agenda Topics

- RAC Program History and Background
- Part D RAC Audit Process
  - Pre-Audit Phase
  - Audit Phase
  - Post-Audit Phase
- Wrap Up

A02207

Part D RAC Program Audit Phases

- **Pre-Audit:** CMS determines audit criteria and scope to conduct audits of previous Medicare Part D payments
- **Audit:** The RAC conducts improper payments analyses and impact calculations and notifies the SO of the findings, including the demanded amount
- **Post-Audit:** Identified improper payments are collected from SOs. If an SO feels the RAC findings are in error, this is also the phase in which an SO is provided opportunity to appeal

Each of these audit phases is discussed in greater detail in the following slides

A02208

RAC Overview Agenda Topics

- RAC Program History and Background
- Part D RAC Audit Process
  - Pre-Audit Phase
  - Audit Phase
  - Post-Audit Phase
- Wrap Up

A02209

CMS Audit Issues

CMS mandates review of contracts by issue type for a specified audit year and audit issue

Planned Part D RAC audit issues include:

- **Excluded Providers:** The Part D RAC reviews PDE records submitted for Part D drugs prescribed and filled by providers who were excluded from Medicare at the time of the claim
- **Duplicate Payments:** The Part D RAC reviews PDEs submitted for the same beneficiary, same medication for the same or closely matching dates
- **Direct and Indirect Remuneration (DIR):** The Part D RAC reviews information submitted to CMS regarding DIR to determine whether amounts reported and used for reconciliation match supporting documentation and actually-incurred costs

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A02210

New Issues Review Board (NIRB)

Additional audit issues may be proposed through the New Issues Review Board (NIRB)

- The NIRB is a multi-member entity within CMS
  - considers potential audit issues and their potential suitability for the RAC program
- CMS, the RAC, SOs, and other stakeholders are encouraged to submit as many potential audit issues as desired to the NIRB for consideration
- CPI leads the NIRB and reaches out to additional Subject Matter Experts (SMEs) within CMS, as appropriate

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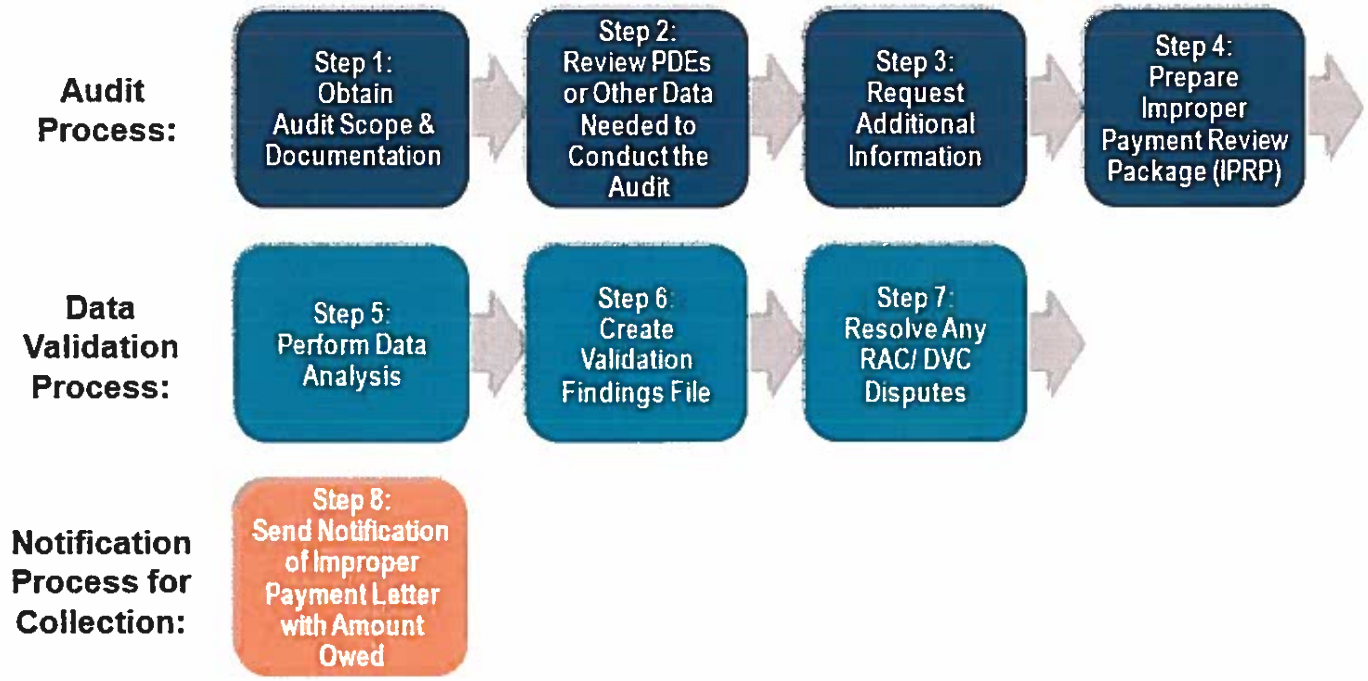
A02211

RAC Overview Agenda Topics

- RAC Program History and Background
- Part D RAC Audit Process
  - Pre-Audit Phase
  - **Audit Phase**
  - Post-Audit Phase
- Wrap Up

A02212

RAC's Multi-step Process Outline



A02213

The RAC Audits Steps

- **Step 1: Obtain Supporting Documentation**
  The RAC must obtain the appropriate documentation from CMS
- **Step 2: Review PDEs or Other Data Needed to Conduct the Audit**
  After the documentation is compiled, the RAC can conduct analyses and impact calculations on audit data to identify improper payments
- **Step 3: Request Additional Information**
  If an improper payment is identified, the RAC may send a Request For Additional Information (RFI) to the SO
- **Step 4: Prepare IPRP**
  After the RAC identifies an improper payment, it compiles an IPRP, which contains the audit issue, audit year and contract number along with supporting documentation identifying the impacted PDE records that support improper payment findings

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A02214

The RAC Audits Steps

- **Step 5: Perform Data Analysis Check**
  The Data Validation Contractor (DVC) receives the IPRP and performs an analysis of the IPRP along with a sample of the associated PDE records
- **Step 6: Create Validation Findings File**
  The DVC creates an IPRP Validation Findings file which includes its analysis and supporting documentation; along with a status of its findings
- **Step 7: Resolve RAC/DVC Findings Disputes**
  If the DVC and the RAC cannot resolve a dispute; the RAC shall notify CMS. CMS is the final decision maker to resolve disagreements on improper payment findings between the DVC and the RAC after they have exhausted all other means

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A02215

The RAC Audits Steps

- **Step 8: Send Notification of Improper Payment Letter** Specifying Amounts Owed
  Once the IPRP has been submitted and validated, a Notification of Improper Payment Letter is formally sent to the SO specifying the amount of improper payments identified, the process for payment, and information regarding appeal

A02216

RAC Overview Agenda Topics

- RAC Program History and Background
- Part D RAC Audit Process
  - Pre-Audit Phase
  - Audit Phase
  - Post-Audit Phase
- Wrap Up

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A02217

RAC Post Audit

RAC will remain involved for Post Audit issues:

- Notification of Improper Payments Letters are sent and identified improper payments are collected from SOs
- Appeal and payment information will be sent along with Notification of Improper Payment Letter
- RAC will assist CMS on appeal issues
- Post audit CMS communication with SOs may involve the RAC

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A02218

RAC Overview Agenda Topics

- RAC Program History and Background
- Part D RAC Audit Process
  - Pre-Audit Phase
  - Audit Phase
  - Post-Audit Phase
- **Wrap Up**

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DP1145

Appendix

The terms below explain some of the key concepts of the Recovery Audit Contractor (RAC) Program

A02220

- **CPI:** CMS' Center for Program Integrity serves as CMS' focal point for all national and state-wide program integrity, fraud and abuse issues in the Medicare and Medicaid programs, and the Children's Health Insurance Program (CHIP). CPI is leading the Part D RAC implementation

- **DVC:** The Data Validation Contractor (DVC) reviews a sample of improper payment findings made by the RAC to validate accuracy. The RAC is unable to recoup overpayment without DVC validation. CMS has contracted with Livanta as the DVC

* Improper Payments: OMB Circular A-123, Appendix C

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The terms below explain some of the key concepts of the Recovery Audit Contractor (RAC) Program (cont.)

A02221

- **Improper Payment:** An improper payment* is any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative, or other legally applicable requirements including, but not limited to:
  - Payments made to ineligible recipients or for ineligible services
  - Duplicate payments
  - Payments for services not received
  - Payments for the incorrect amount
  - Payments deemed to be insufficiently supported by documentation

* Improper Payments: OMB Circular A-123, Appendix C

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The terms below explain some of the key concepts of the Recovery Audit Contractor (RAC) Program (cont.)

A02222

- **IPRP:** The Improper Payment Review Package (IPRP) is an improper payment file and the supporting documentation for a particular audit issue by contract and year

- **PDE:** Prescription Drug Event data are records submitted every time a beneficiary fills a prescription under Medicare Part D Program

- **RAC:** The Recovery Audit Contractor (RAC) detects and corrects past improper payments to Medicare Providers and Sponsoring Organizations, and implements procedures to help CMS, SOs Medicare carriers, Fiscal Intermediaries, and Medicare Administrative Contractors (MACs) implement actions to prevent future improper payments

The terms below explain some of the key concepts of the Recovery Audit Contractor (RAC) Program (cont.)

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- **SO:** A Sponsoring Organization (SO) is a private organization that contracts with CMS to administer Medicare Parts C or C & D benefits and may offer several different types of Part C and/or D plans. SOs include, but are not limited to, Part D Prescription Drug Plans (PDPs), Medicare Advantage Organizations (MAOs) and Medicare Advantage Prescription Drug Plans (MA-PDPs)

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Medicare Part D and RAC Program Background

- **Medicare Modernization Act (MMA):** Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173) was signed into law on December 8, 2003. The MMA established a new voluntary outpatient prescription drug benefit under Part D of Title XVIII of the Social Security Act (the Act)

- **The Tax Relief and Health Care Act of 2006:** Implemented the RAC program as a demonstration project to identify and prevent improper payments in fee-for-service (FFS) Medicare by analyzing previously paid Medicare Parts A and B claims

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Medicare Part D and RAC Program Background (cont.)

- **The Patient Protection and Affordable Care Act (ACA):** enacted in March 2010, required CMS to expand the RAC program to the Medicare Part C (Medicare Advantage) and Part D (Prescription Drug Benefit) programs
  - Section 6411(b) of ACA expands the use of RACs to all of Medicare (Title XVIII) amending the existing FFS RAC statute at section 1893(h) of the Act
  - The amendments provide CMS with general authority to enter into contracts with RACs to identify and reconcile overpayments and underpayments in Medicare Parts C and D

Medicare Part D RAC Program Contacts:

For Technical Questions About the Part D RAC Program, contact:

PartD_RACCommunications@cms.hhs.gov

Affidavit of Christopher Mucke

EXHIBIT 20

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

ACLR, LLC	)	
	)	
Plaintiff	)	
	)	
v.	)	**Civil Action No. 15-767 and 16-309**
	)	(Judge Campbell-Smith)
THE UNITED STATES	)	
	)	
Defendant	)	
	)	

AFFIDAVIT OF CHRISTOPHER MUCKE IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

I, Christopher Mucke, am competent to testify on the matters stated herein and make the following statements on personal knowledge and under oath:

1. I am the Managing Principal of ACLR, LLC and am over 18 years of age.

2. ACLR, LLC is recovery auditing firm whose clients have included the Centers for Medicare & Medicaid services, state governments and some of the largest manufacturing, automotive, pharmaceutical, and aviation companies in the world.

3. I have over 30 years of recovery audit experience including federal and state statutory and regulatory payment compliance; data analysis; statistical sampling; and litigation support services with a particular emphasis in prescription drug benefit and federal, international, and state sales, use, excise, and value added taxation payment recoveries. I am a graduate of the University of Tennessee, Chattanooga and a former Certified Public Accountant, licensed in Maryland. I have been a guest lecturer at numerous business organizations and the Georgia

Institute of Technology and have authored or co-authored white papers and articles on statutory compliance and statistical sampling recovery audit methodologies.

4. Plan sponsors participate in Part D by submitting a bid, which consists of a plan formulary, an estimate of the total prescription drug costs anticipated for a calendar year period ("plan year" or "PY"), and the costs associated with administering the prescription drug plan ("PDP").

5. CMS approved plan sponsor bids are awarded a contract on an annual basis.

6. Each plan year, CMS makes monthly prospective payments to plan sponsors.

7. These payments are based on approved contract costs and consist of three subsidies: the direct subsidy, which is based on the plan's approved bid and adjusted for health status and beneficiary premiums; the reinsurance subsidy, a payment consisting of 80 percent of a beneficiary's allowable reinsurance costs; and the low income cost-sharing ("LICS") subsidy, which is paid by CMS on behalf of eligible low income individuals.

8. As a condition of payment, plan sponsors must submit information necessary for CMS to carry out Part D payment provisions.

9. Approximately one year after the end of each plan year in a process known as final reconciliation ("reconciliation"), CMS calculates the difference between prospective amounts paid for the reinsurance and LICS subsidies to determine amounts owed to or amounts due from plan sponsors.

10. CMS also makes a risk sharing payment, designed to permit plan sponsors and CMS to share excessive profits or losses that occur between bid estimates and actual drug costs.

11. Once all amounts have been calculated, CMS makes a reconciliation payment to plan sponsors. At its discretion, CMS reserves the right to recalculate the original payments made to plan sponsors at final reconciliation. This recalculation, known as reopening, typically occurs four years after final reconciliation and consists of recalculating plan year Part D reinsurance, LICs, and risk sharing payment amounts owed as a result of additional plan sponsor PDE submissions made after final reconciliation.

12. PDEs used to calculate amounts owing at final reconciliation, also known as "reconciled" or "final action" PDEs are the basis of ACLR improper payment audits.

13. ACLR reviews final reconciliation PDEs to make determinations of payment veracity and to identify and recover Part D improper payments.

14. In its evaluation of PDE records, ACLR relied on three components of the PDE records: fields which identified a unique prescription, fields pertaining to individual dispensing events for each prescription, and financial fields used to calculate the Part D payment for each improper PDE claim.

15. To uniquely identify each prescription, ACLR relied on concatenating the health insurance claim number ("HICN"), which uniquely identifies each Part D beneficiary; the prescription/service reference number ("SRN"), which is a unique number assigned by the pharmacy for each prescription within any particular plan year; and the service provider and prescriber field, which consists of a unique number assigned to the pharmacy location that dispensed the drug and the prescriber that wrote the prescription.

16. To identify individual dispensing event information for each prescription, ACLR relied on the product service identification field, which used a National Drug Code ("NDC") to identify the drug dispensed; the dispensing status field, which identifies a partial fill as "P" and

the final fill of a partial fill as "C"; and the fill number, which identifies an original fill as "0," the first refill as "1," second refill as "2," and so on.

17. To calculate Part D improper payment amounts, ACLR sums applicable cost and payment fields associated with improper payment PDEs and recalculates final reconciliation by calculating the difference between amounts paid for reinsurance, LICs, and risk sharing during final reconciliation and amounts that would have been paid had the improper payments not occurred. The sum of which constitutes total improper payment amounts owing.

18. CMS was reimbursed for improper payments through the use of an "interim adjustment" process whereby amounts associated with the reinsurance and low income cost subsidies are removed from current plan year subsidy payments. CMS was reimbursed for risk sharing improper payments during the reopening process. ACLR was paid its contingency fee only from CMS's reimbursement from the interim adjustment.

19. To conduct the plan year 2007 duplicate payment audit, ACLR relied on plan sponsor certifications that PDE records had been accurate, complete, and truthful and that the data was in compliance with HIPAA simplification rules and matched PDE records containing the same HICN, SRN, pharmacy, and fill number to identify individual prescriptions and eliminate duplicates arising from permissible dosage changes by contract. ACLR did not include duplicates arising from PDE records where the fill number was equal to zero.

20. To eliminate permissible partial fills, ACLR reviewed the dispensing status field on each PDE to determine whether duplicative fill numbers arose as the result of a partial fill and eliminated those partial fills from further review.

21. Upon elimination of permissible partial fills, ACLR sorted the remaining prescriptions by the date the PDE was filled by the pharmacy ("Date of Service") and identified

the earliest PDE Date of Service as the original payment and subsequent PDEs with the same Date of Service as duplicate improper payments.

22. Using this methodology, ACLR identified plan year 2007 Part D duplicate payment amounts totaling $313,808,241.

23. Efforts by ACLR to conduct a PY 2007 duplicate payments audit special study similar to that approved for the PY 2007 excluded provider audit were refused by CMS.

24. After ACLR raised concerns about CMS contract compliance in April 2012, CO Schultz informed ACLR that CMS would not consider financial restitution for delays, additional appeals, and review requirements unless ACLR removed the base year contract request for equitable adjustment, which ACLR refused to do.

25. As of April 2012, ACLR had not received any payment under the Part D RAC Contract as ACLR had not been allowed to pursue the recovery of any improper payments.

26. ACLR estimated costs associated with CMS delays during the 2012-2013 period amounted to $2,668,553.

27. On January 2, 2014, ACLR submitted its NAIRP for plan year 2009-2012 duplicate payments.

28. Under the approved methodology in the plan year 2009-2012 duplicate payments NAIRP, ACLR identified duplicate payments using CMS's Uniform Examination Program ("UEP") duplicate payment protocol whereby potential duplicate payments are identified as "PDEs submitted to the same beneficiary, for the same medication, and on the same/very close dates."

29. To match individual PDE fields, ACLR matched PDE records containing the same contract and prescription drug plan, HICN, NDC, and fill number fields.

30. To determine the "same/very close dates," the NAIRP contained an early refill methodology, which consisted of comparing the days' supply of the originating PDE record to the days elapsed between the originating PDE and subsequent matching PDE record and calculating the days between each PDE's respective Date of Service. Potential duplicate payments were identified when the days elapsed were less than 50% of the days' supply of the originating PDE record.

31. The approved plan year 2010-2012 duplicate payments NAIRP audit methodology precluded the review of PDEs associated with long term care facilities and mail order pharmacies and these records were eliminated from ACLR's audit.

32. ACLR submitted its RFI findings to CMS on June 10, 2014.

33. In addition to its validation work for the Duplicate Payment RFI Report, the DVC deviated from the methodology approved in the plan year 2009-2012 duplicate payment NAIRP and applied a "dosage increase" percentage to identify possible permissible dosage changes.

34. By applying a revised methodology that was not part of the approved NAIRP, the DVC reviewed PDE data fields not contained within CMS data submissions to ACLR for the 2011 and 2012 plan years duplicate payment audit causing CMS to only approve the release of plan year 2010 duplicate payment RFIs.

35. On July 8, 2014, ACLR submitted the RFIs for improper 2010 duplicate payments to plan sponsors requiring, in accordance with the Part D RAC Contract option year one statement of work, that evidentiary support be submitted within 60 days.

36. On October 22, 2014, CMS instructed ACLR to apply a revised CMS methodology, based on its interpretation of the DVC report, to the 2010 duplicate payment RFI

PDEs to eliminate possible permissible dosage changes and to submit new RFI IPRPs to CMS for subsequent resubmission to plan sponsors.

37. Based upon ACLR's belief that CMS's direction on January 8, 2015 to resubmit ACLR's IPRPs in accordance with CMS's revised methodology was an additional Part D RAC Contract deviation, ACLR referred the matter to CO Hoey.

38. ACLR's contingency fee rates for the $15,909,552 plan year 2010 duplicate payments identified by ACLR was $2,209,146.

39. The PDE record contains three detailed cost fields: ingredient cost paid, dispensing fee paid, and total amount attributed to sales tax.

40. ACLR reviewed reconciled PDE records for plan years 2012-2013 and identified all PDE records containing sales tax amounts greater than $0.00.

41. ACLR then identified the addresses for all pharmacies and reviewed applicable state and local tax laws to identify pertinent sales tax laws and their application to the sales tax PDEs ACLR had identified.

42. During this review, ACLR identified sales taxes that were billed on PDEs from five states that did not impose sales taxes, sales taxes that were billed in the states of Louisiana and Minnesota that exempted PDEs where such taxes were statutorily exempt, and sales tax charges billed at impermissible tax rates exceeding 50% of PDE drug costs.

43. The states of Alaska, Delaware, Montana, New Hampshire, and Oregon do not impose sales taxes.

44. There are no taxing jurisdictions that impose sales taxes at rates exceeding 50% of the actual drug costs in Part D PDEs submitted to CMS for payment.

45. ACLR's NAIRP identified $626,326,618 in improper payments on the plan year 2012 and 2013 sales tax NAIRP for Minnesota, the five states that do not charge sales taxes, and sales tax charges billed at impermissible tax rates exceeding 50% of PDE drug costs entitling ACLR to a contingency fee on those improper payments of $75,459,194.

46. During the course of the Part D RAC Contract, ACLR identified and submitted to CMS Part D improper payments totaling $3 billion.

47. However, through the date of this filing, CMS Part D improper payment collections, upon which ACLR was paid, totaled $11.9 million.

I declare, under penalty of perjury, that the foregoing is true and correct.

Executed this 25th day of April, 2018 at Ann Arbor, MI.

Christopher Mucke

STATE OF MICHIGAN
COUNTY OF Washtenaw, To-wit:

This foregoing instrument was acknowledged before me this 25th day of April, 2018 by Nicole Schilde.

Notary Public
Notary Number
My commission expires: 07/15/2020

NICOLE SCHILDE
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF WASHTENAW
My Commission Expires 07/15/2020
Acting in the County of Washtenaw